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FOREWORD

The American Society for Quality Control is pleased to publish these Transactions of papers presented at our 32nd Annual Technical Conference in Chicago, Illinois, May 8-10, 1978. Although these papers have been screened by the sponsoring Division or Technical Committee, the Society assumes no responsibility for the contents of the papers printed here. Some of these papers may later be reviewed by an editorial board of the Society and may appear in one of our regular publications. We hope that you will find these papers both educational and inspirational.

Lawrence R. Dorsky,
Vice President, Publications

COMMENTS - 32nd ANNUAL TECHNICAL CONFERENCE

Jay W. Leek
Technical Program Chairman

Quality--True Test of Management, the Theme for this year's Conference is indeed appropriate and timely. The era in which we find ourselves challenges our management skills in dealing with the very basics of our social and industrial life.

The seemingly endless degradation of family life, the continuous social upheaval and encounters, environmental exploitation, governmental control, and industrial problems pose unique but certainly rewarding challenges. Some of these we must face in the next decade include:

- a. Deciding the role we can play in our industrial society.
- b. Selecting operating goals which support the "Good Customer" concept.
- c. Understanding management actions implicit in the formula for business "Revenue minus Cost equals Profits" and the skills and techniques necessary to fulfill this promise.
- d. Planning for lower administrative costs and managing throughout to attain lower working capital requirements.
- e. Developing organizations utilizing people having contemporary educations, humanitarian ethos, and goals not weighted heavily in money and materialistic incomes.
- f. Learning to be an effective agent of change. To go on as we are brings additional problems.

Strategic planning today needs more than the normal lip service. Quality and Reliability professionals need to change their image from the tactician to strategists, more skilled in forward planning and thinking. Doing so will find a truly supportive management in attaining our goals and objectives and will assist in greater self-actualization, both in our social and industrial endeavors.

The Committee joins me in hoping you will find our Conference informative, educational, stimulating and satisfying. The Committee has done an outstanding job in its preparation and I would like to use this media to extend my heartfelt thanks for their outstanding support and excellent cooperation.

Welcome to Chicago and the Palmer House and trust your stay will be enjoyable and this Conference the best ever.

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QUALITY MODELING

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ABSTRACT

A model is suggested for quantifying a generalized manufacturing process unit as a function of time. Through a series of such interconnected models, a total manufacturing operation leading to the deliverable product may be depicted. A graphical interpretation of acceptables and defectives is presented. The key quality parameter is process gain - the ratio of acceptables to defectives. Analysis of model structures is carried out by Laplace transform methodology.

TEXT

System analysis literature is replete with the application of electrical equivalents as an interpretive vehicle for the modeling and performance prediction of mechanical, electromechanical and hydraulic systems. Assigning transfer functions representing the analog of each uniquely contributing member of a system facilitates both analysis and physical understanding of the system dynamics.

A quality model for a manufacturing process unit may be constructed through such a series of electronic circuit analogies. The kernel of the quality model - the Process Unit - is comprised of the least number of specific operations required to produce a definable product - a process followed by an inspection.

As a preliminary step, it is essential that the quality model be placed in its proper perspective in the life cycle of a product. In the general case, it may be assumed that every process will produce an output comprised of acceptables and defectives. Since no process is without flaws, there is only a design-intended probability that it will produce a yield comprised principally of acceptables. In this context, the following definitions are suggested:

Quality Control is a system of regulatory controls designed to maximize the probability that a product will conform to its specification requirements.

Product Assurance, which encompasses Quality Control and Reliability Control, is now defined to provide an interlocking relation between both:

Product Assurance maximizes the probability that a product manufactured in conformance with its specification requirements will continue to meet those requirements under prescribed operational conditions for a specified time.

Quality is a specified group of quantifiable characteristics that determine the probability of a product conforming to its specification requirements.

The Quality Control time span influencing the manufacturing process may be considered small by comparison to the complete life cycle of a product, with the desired objective of $MTBF \gg \text{fabrication time}$ (Figure 1). An exception exists for certain specialized products such as explosives, where fabrication time $\gg MTBF$.

To make the definitions of Quality Control and Product Assurance statistically general, their respective probabilities may be further qualified by confidence levels.

The significance of quality modeling rests in its quantification of the relation between process yield and attrition. Quality engineers are concerned with achieving satisfactory process yields, and are chartered to analyze and correct processes falling short of expectations. Materiel personnel share these concerns, and are not only mandated to supply the commodities listed on each bill of material, but are required to anticipate projected losses, and extend their purchases accordingly to maintain the material requirements for each process. Through a better understanding of process quality dynamics and their interrelation, the best intentions of Pareto may be served in terms of prioritizing analysis and correction action, and quality engineers may eventually be able to assist Materiel personnel to more accurately forecast their requirements. Similarly, since the correction of defective material entails additional manpower, assistance may ultimately be rendered managers concerned with the impact of defective material on personnel requirements.

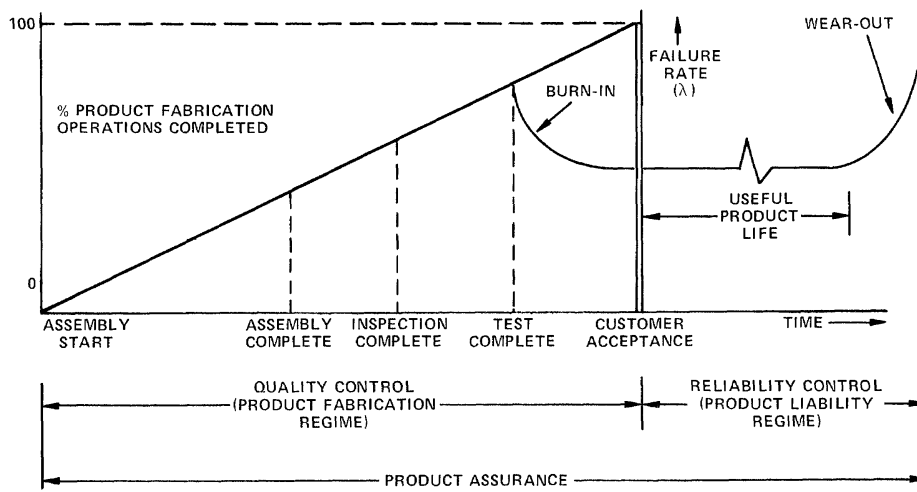


Figure 1.

A series of postulates follow, leading to the construction of a representative quality model for a process unit.

Postulate 1. Process Unit

A Process Unit is the smallest manufacturing operational sequence capable of producing a functional product to specification requirements, consisting of a process followed by an inspection.

Postulate 2. Process Output (P)

Every process output, P, consists of acceptables and defectives (conforming and non-conforming products), defined as P_a and P_d , where $|P| = |P_a| + |P_d|$.

The gain of a process may be expressed as the ratio of its acceptables to its defectives.

Postulate 3. Process Gain (G)

The gain of any process is: $|G| = \left| \frac{P_a}{P_d} \right|$

Postulate 4. Significance of P_d

Since the defectives do not contribute to the conforming output of a process, they are postulated as being in quadrature with the acceptables.

Some defectives may be recoverable by rework or repair, where other defectives have zero recovery potential and are considered scrap.

Postulate 5. Composition of P_d

Process output defectives are comprised of recoverable and non-recoverable components. $P_d = P_{dR} + P_{dS}$, where P_{dR} represents the recoverable defectives, and P_{dS} represents the non-recoverable defectives (scrap).

Postulate 6. Inspection Effectiveness

The effectiveness of inspection may be measured through its ability to attenuate defectives (filtering of defectives): $\alpha = \frac{P_{ds}}{P_{ds'}}$, where α is the attenuation ratio of defectives and $P_{ds'}$, the residual defectives after inspection.

Postulate 7. Process Output, Vector Notation

A process output may be represented by the vector summation of its P_a and P_d components (Figure 2):

$$\bar{P} = \bar{P}_a + \bar{P}_d$$

Where $\bar{P}_a = \bar{P} \cos \theta$

$\bar{P}_d = \bar{P} \sin \theta$

$|\bar{P}| = \sqrt{\bar{P}_a^2 + \bar{P}_d^2}$

and $\theta = \tan^{-1} \frac{\bar{P}_d}{\bar{P}_a}$

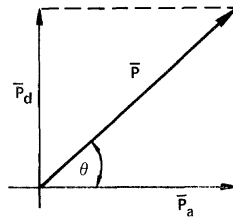


Figure 2.

Postulate 8. Inspection

Perfect inspection is analogous to a phase-sensitive detector in that it separates \bar{P} into its \bar{P}_a and \bar{P}_d (in-phase and quadrature) components.

Postulate 9. Generalized Operational Statement

In that the probability exists that all operational steps leading to an accepted product may exhibit some degree of imperfection in producing defectives as well as acceptables, vector notation may be employed to characterize each operation, leading in sum total to the accepted product.

Postulate 10. Generation of Defectives

Defectives may be generated through the input of nonconforming materials to a process (external), or through process deficiencies (internal).

Postulate 11. Analysis and Corrective Action (H term)

Analysis and corrective action (ACA) provides negative feedback to a process so as to exclusively operate on and attenuate its defective (\bar{P}_d) output.

Postulate 12. Rework and Repair

Rework and repair operate on recoverable defectives, rotating the \bar{P}_{dr} vector $\frac{\pi}{2}$ radians to the \bar{P}_a axis.

Postulate 13. Negative Acceptables (\bar{P}_{an})

Negative acceptables result from the erroneous identification of good material as bad material (Type I error).

Postulate 14. Negative Defectives (\bar{P}_{dn})

Negative defectives result from the erroneous identification of bad material as good material (Type II error).

Postulate 15. Start-up Delay

The start-up delay of a process is defined as the transient time between the start of a process and the time when the process output per unit time interval becomes constant. Included in this time are such factors as operator learning curve, adjustment of production machinery, and corrections to drawings and/or specifications.

Postulate 16. Processing Time

Processing time is defined as the period required to produce one acceptable, following the start-up delay of a process (Figure 3).

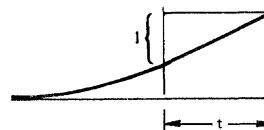


Figure 3.

Postulate 17. Process Function

Assuming a constant input of material, a process performs the operation of a converter/integrator, producing a linearly rising output as a function of time, in assembling raw material to meet product specifications. Utilizing postulates 2, 5, 7, 13 and 14, the output of a process unit is graphically depicted (Figure 4).

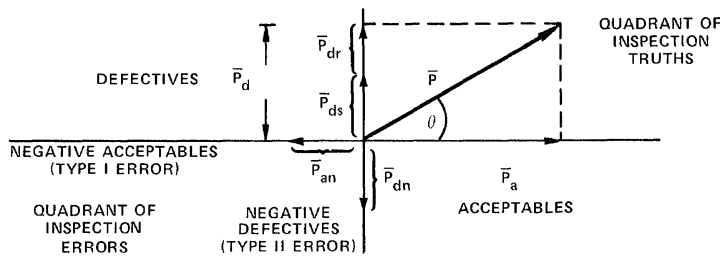


Figure 4.

Upon correction of the Type I and Type II errors, and separation of defectives into recoverable and non-recoverable categories, \bar{P}_a is increased by \bar{P}_{dr} and \bar{P}_{an} , and \bar{P}_d is reduced by \bar{P}_{dr} , and increased by \bar{P}_{dn} (Figure 5):

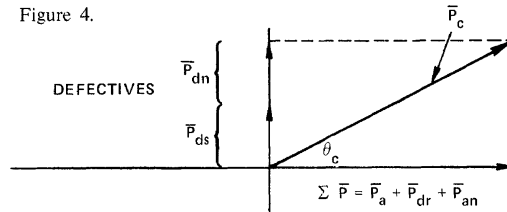


Figure 5.

where \bar{P}_c and θ_c are the corrected process unit output and phase angle. The output of a series of such corrected process units may be combined as (Figure 6):

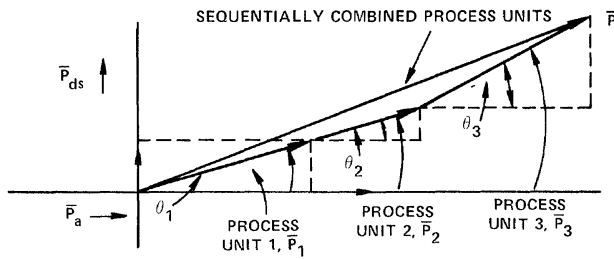


Figure 6.

Where $\prod_{n=1}^m \bar{P} = \bar{P}_1 \cdot \bar{P}_2 \cdot \bar{P}_3 \dots \bar{P}_m$, and $\prod_{n=1}^m \bar{P}$ represents the end item derived from sequential process units.

The processing function may be modeled as (Figure 7):

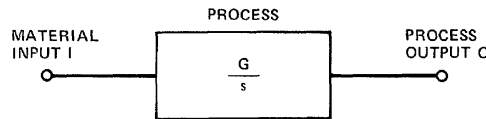


Figure 7.

Where G is the process gain and s is the Laplace transform operator. Assuming zero initial conditions, and a step input of material $\frac{1}{s}$, $O(s) = \frac{1}{s} \cdot \frac{G}{s}$, and $O(t) = IGt$.

$O(t) = IGt$, is a function describing a linear integrator whose output is proportional to the material input, the process conversion gain, and increases with time. Postulate 15, Start-Up Delay, is omitted in the interests of simplicity, though in practice, the linear Processing Time (Postulate 16) is not achieved immediately, unless the product had been produced for a period sufficient to account for all Start-Up Delay factors. A more rigorous treatment includes a representative start up function, $O = IGt^2$, which prevails until its slope matches that of the integrating function, t^2 denotes an accelerated learning curve (Figure 8):

$$\text{For } O = IGt^2, \frac{dO}{dt} = 2IGt.$$

The slope of the integrator is $\frac{dO}{dt} = 2IG$. When $t = \frac{1}{2}$, $\frac{dO}{dt} = IG$, and the functions are joined at $O = IG \left(\frac{1}{2}\right)^2 = \frac{IG}{4}$ (Figure 8):

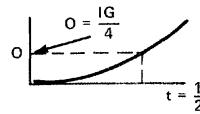


Figure 8.

Inspection may be modeled as (Figure 9):

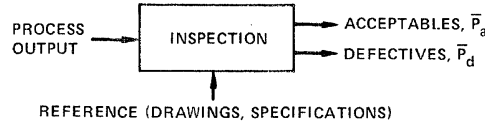


Figure 9.

In terms of its electronic analogy, the process output consisting of quadrature and in-phase components ($\bar{P}_a + \bar{P}_d$), is fed to a phase-sensitive detector. Process drawings and specifications are equivalent to the reference voltage in the phase-sensitive detector, and supply the baseline through which the separation is made of the process output into acceptables and defectives.

Assuming perfect inspection, the acceptables are routed to the next product assembly operation, and the defectives are routed to the ACA operation (H), whether they may be due to external or internal causes. The output of the H operation is utilized as a source of negative feedback for defective material inputted to a process, and as an attenuator of internally generated defectives. Because of the unique property of perfect inspection to separate a process output into its \bar{P}_a and \bar{P}_d components, negative feedback is selectively applied, so as to reduce \bar{P}_d , while leaving \bar{P}_a undisturbed. The simplified model depicting the H function is (Figure 10):

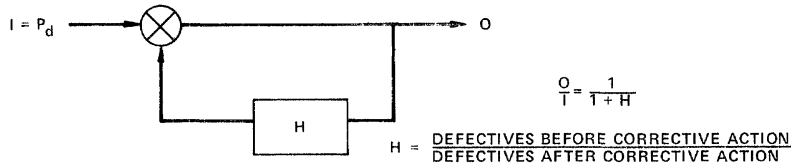


Figure 10.

When $H \gg 1$, $\frac{O}{I}$ may be simplified as: $\frac{O}{I} = \frac{1}{H}$, indicating that the process output of defectives is inversely proportional to the effectiveness of corrective action. With the defectives attenuated by a factor of $\frac{1}{H}$, the new process gain, improved by ACA, is: $G' = H \left| \frac{P_a}{P_d} \right|$. The simplified process unit model with ACA feedback is now developed for the acceptable and defective output components.

Considering the acceptable part of the output: $\frac{O}{I} = \frac{G_a}{s}$ where G_a is that part of the process producing P_a acceptables, and $O = \frac{G_a}{s} I$. For a step input of $\frac{I}{s}$, taking the inverse transform:

$$O(s) = \frac{I G_a}{s^2}, \text{ and } O(t) = I G_a t.$$

where the acceptable process output increases linearly with time, and is proportional to the material input and process conversion gain. Considering the defective part of the output: $\frac{O}{I} = \frac{G_d}{s}$ where G_d is that part of the process producing P_d defectives. In this case, the discriminator characteristic of inspection will provide a feedback signal to the ACA (H) function, and the loop will be closed for defectives. For a step

input of $\frac{P_d}{s}$, $O(s) = \frac{\frac{P_d}{s} \cdot \frac{G_d}{s}}{1 + \frac{G_d H}{s}} = \frac{P_d G_d}{s(s + G_d H)}$. Taking the inverse transform:

$$O(t) = P_d G_d \left[\frac{1 - e^{-G_d H t}}{G_d H} \right], \quad O(t) = \frac{P_d (1 - e^{-G_d H t})}{H}$$

As t increases definitely, the exponential term may be disregarded, and $O(t) \rightarrow \frac{P_d}{H}$. The same result could have obtained using the final value theorem for Laplace transforms: the process output of defectives is an exponential function, asymptotic to $\frac{P_d}{H}$ (Figure 11):

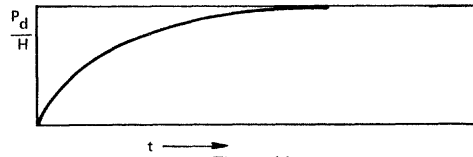


Figure 11.

Note that the H term is a function of the effectiveness of ACA, and is measured by its ability to attenuate defectives.

As before, the adjusted process gain with ACA becomes: $G' = H \left| \frac{P_a}{P_d} \right|$. The model depicting rework and repair is (Figure 12):

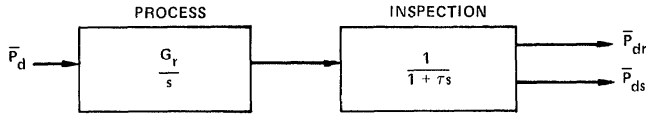


Figure 12.

The P_d defectives have been converted by the Rework and Repair integrating function into acceptables and non-recoverable defectives (scrap). The P_{dr} component is summed up with the initial P_a component and the P_{an} negative acceptables to form the total acceptable output $\Sigma P = P_a + P_{dr} + P_{an}$. Providing it is cost effective, P_{ds} may be subjected to one or more iterations through the Rework and Repair cycle in effort to reduce the amount of scrap and obtain a higher yield of acceptables.

Refining the model further, it is observed that the attenuation of defectives does not occur immediately, as a finite period (T) is required to analyze the cause of defectives and develop responsive corrective action. The transfer function for ACA is of the form $H e^{-Ts}$ where T is the dead time prior to the attenuation of defectives.

The inspection function does not occur immediately either, but is subject to a lag time constant τ , and a transfer function of the form $\frac{1}{1+\tau s}$. As inspection rarely generates defectives, it is considered a unity gain function.

Connecting the transfer function building blocks to form the complete model (Figure 13):

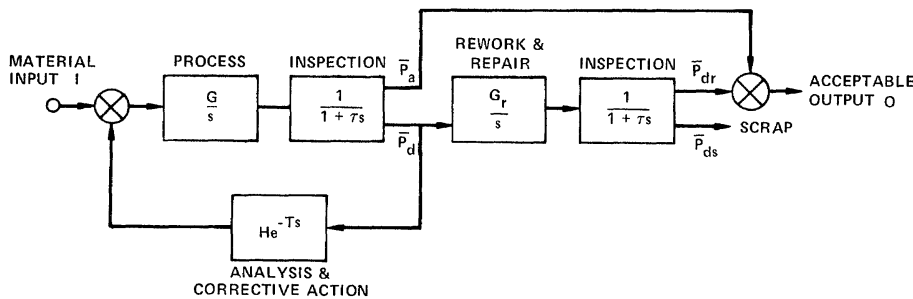


Figure 13.

As the dead time required to complete the analysis of defectives and develop the required corrective action is equivalent to opening the ACA feedback loop, the defectives will not be attenuated during the period T , and consequently, the process gain will not be improved during the interval. The output of the process unit can be developed as the sum of two time dependent functions: that without ACA, followed by that with ACA.

During the interval T, when ACA is under development:

$$\frac{O}{I}(s) = \frac{G}{s} \frac{1}{1 + \tau s} = \frac{G}{\tau s \left(s + \frac{1}{\tau} \right)}$$

$$\frac{O}{I}(t) = \frac{G}{\tau} \frac{\left(1 - e^{-\frac{t}{\tau}} \right)}{\frac{1}{\tau}} = G \left(1 - e^{-\frac{t}{\tau}} \right), \text{ for } T \gg t, \frac{O}{I}(t) \approx G$$

With

$$I(s) = \frac{1}{s}, O(s) = \frac{IG}{s^2} \cdot \frac{1}{1 + \tau s}, O(t) = IG\tau \left(e^{-\frac{t}{\tau}} + \frac{t}{\tau} - 1 \right)$$

When

$$T \gg \tau, \frac{T}{\tau} \gg 1, \text{ and } e^{-\frac{T}{\tau}} \approx 0$$

O(t) may be approximated as: O(t) ≈ IGt, an integrating function where O(t) ≈ IGT at the end of the interval T.

The output as a function of time is simply: |P| = |P_a| + |P_d| where the process unit output is determined by the material input I, and the process unit gain $G = \left| \frac{P_a}{P_d} \right|$.

Upon completion of the ACA interval, the H feedback loop is closed and the response for $\frac{O}{I}(s)$ is in the form: $\frac{O}{I}(s) = \frac{G(s)}{1 + G(s) \cdot H(s)}$.

Substituting transfer functions: $\frac{O}{I}(s) = \frac{\frac{G}{s} \left(\frac{1}{1 + \tau s} \right)}{1 + \frac{GH}{s} \left(\frac{1}{1 + \tau s} \right)} = \frac{G}{s(1 + \tau s) + GH}$ Rearranging terms and multi-

plying and dividing by H: $\frac{O}{I}(s) = \frac{1}{H} \cdot \frac{\frac{GH}{s^2 + \frac{s}{\tau} + \frac{GH}{\tau}}}{\frac{GH}{s^2 + \frac{s}{\tau} + \frac{GH}{\tau}}}$ Which is in the form: $\frac{\omega_n^2}{s^2 + 2\zeta\omega_n s + \omega_n^2}$, where

$\omega_n = \sqrt{\frac{GH}{\tau}}$ and $\zeta = \frac{1}{2\sqrt{GH\tau}}$. Depending upon the values of G, H and τ , the quadratic function may assume various degrees of damping. If the inspection time constant τ is large, the process unit will exhibit an underdamped condition. The economics of most manufacturing operations generally dictate that τ be small compared to the unit fabrication time.

The inverse transform for the quadratic is of the form:

$$\frac{O}{I}(t) = \frac{1}{H} \left[\frac{1}{\omega_n \sqrt{1 - \zeta^2}} e^{-\zeta\omega_n t} \sin \omega_n \sqrt{1 - \zeta^2} t \right]$$

With the assumption that the process is at least critically damped ($\zeta = 1$), $\frac{O}{I}(s) = \frac{\omega_n^2}{H(s + \omega_n)^2}$, and

$\frac{O}{I}(t) = \frac{\omega_n^2 t e^{-\omega_n t}}{H}$. The rework and repair operation may be treated in the same manner as a process unit without ACA feedback, assuming a small inspection time constant τ .

Similarly, $\frac{O}{I}(t) \approx IG_I t$, where I is the \bar{P}_d component consisting of recoverable and non-recoverable defectives. It is noted that the rework and repair input of defectives will be reduced by a factor $\frac{1}{H}$ following the time when the ACA loop is closed, by comparison to that during the interval T. Summing up the process unit, and the rework and repair functions: at the completion of time interval T, the process loop transfer function for recoverable defectives is: $\frac{O}{I}(s) = \frac{G}{s} \left(\frac{1}{1 + \tau s} \right) \cdot \frac{G_r}{s} \left(\frac{1}{1 + \tau s} \right)$ and $\frac{O}{I}(s) = \frac{G_a}{s} \left(\frac{1}{1 + \tau s} \right)$ is the transfer function for the acceptable output.

Summing up both transforms:
$$\frac{O}{I}(s) = \frac{G G_r}{s^2 \tau^2} \left(\frac{1}{s + \tau} \right)^2 + \frac{G_d}{s\tau} \left(s + \frac{1}{\tau} \right)$$

Through the preceding methodology, additional functions may be derived that depict other segments of a manufacturing operation.

The stability of a system may be treated by superimposing its output on a control chart (Figure 14):

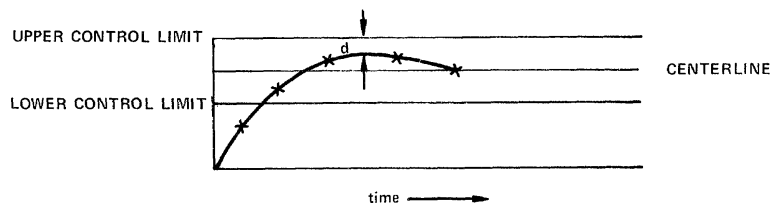


Figure 14.

The transient stability margin of a system may be calculated as the distance between the inflection point, and its nearest control limit:

$$\text{Transient stability} = \frac{d}{\frac{(UCL - LCL)}{2}}$$

The long term stability margin may be calculated as follows (Figure 15):

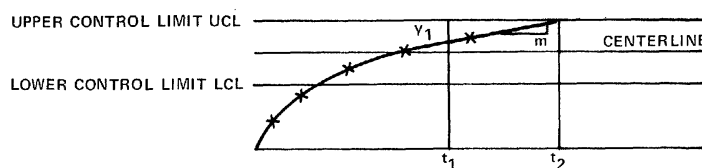


Figure 15.

For this situation, $\Delta t = t_2 - t_1 = \frac{UCL - y_1}{m}$. With a slope m , the process output will intersect the UCL at t_2 , if left uncorrected. Δt is the "time to go" before violating the UCL, indicating the time available for ACA to take effect, if the UCL is to be avoided.

While closed loop analysis may utilize many different methods to determine system stability, the criteria for a stable system as applied to a Process Unit has a different interpretation, i.e., the output may be continuously oscillating, but providing it is confined to the region between the LCL and UCL, the process must be considered stable in terms of its ability to produce an acceptable product. A continuously oscillating servo system would normally be considered indicative of an unstable, and hence, unacceptable condition.

In the sense that the acceptability of a Process Unit is measured by its ability to remain between the UCL and LCL, as prescribed by specifications, generically, it resembles a regulating system more than continuously variable servo system.

ADDITIONAL OBSERVATIONS

1. Further consideration of the inspection function indicates that it should include a defect leakage path to account for less than perfect inspection (Figure 16):

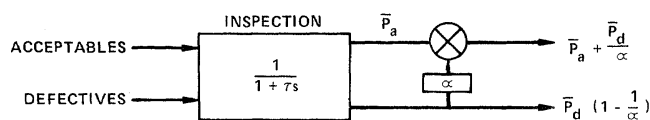


Figure 16.

where α is a function representing the residual defectives after attenuation by inspection, escaping detection and separation into the \bar{P}_a and \bar{P}_d components (Postulate 6).

2. In considering the difference between externally and internally caused defectives, a more rigorous model of a process is depicted (Figure 17):

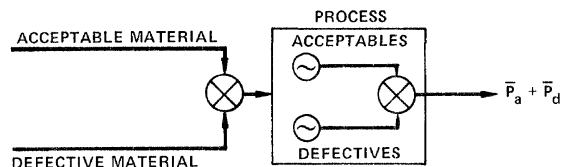


Figure 17.

The process input is the sum of acceptable and defective material. Similarly, the output is the sum of acceptables and defectives. The P_d output component includes both externally caused defectives due to the unplanned input of nonconforming material, plus internally generated defectives due to process imperfections.

3. Though the separation of the Process Unit output into acceptables and defectives has been heretofore assigned exclusively to the inspection function, in practice the operator assigned to perform or monitor the process operation contributes to the inspection function through observing anomalies in the process output. Thus, some degree of defect reduction may actually occur prior to the formal inspection function.

E.O. Codier (Ref. 1) states that $\lambda_{\text{part total}} = \lambda_{\text{intrinsic}} + \lambda_{\text{induced}}$, and believes that λ_{induced} is much larger than $\lambda_{\text{intrinsic}}$. Possible contributions to λ_{induced} are:

- Lack of regularly scheduled operator training and certification
- Unauthorized departures from manufacturing instructions
- Manufacturing instructions that do not reflect component application constraints
- Insufficient process controls
- Arbitrary selection of sampling plans without regard to the probability of accepting a specific percentage of defectives
- Failure to recognize that repaired or reworked assemblies may have degraded reliability
- Inspection oversights
- Inadequate specification controls of critical parameters
- Lack of verification of stress levels.

In particular, the contribution of each of the above to the part total failure rate are unique to each company, and comprise part of its "quality fingerprint." As a functional tool, it is suggested that the failure rates for each predictive entity be increased by a factor related to the percent rejections of each component by comparison to the using population. Should any test failure occur resulting in a component replacement or assembly repair, a failure rate penalty would be exacted. Thus, only those components that remain undisturbed in the entire manufacturing cycle would be characterized by the intrinsic failure rate.

4. Failure Modes and Effects Analysis (FMEA) is a recognized method for revealing sources of design weakness affecting reliability. The FMEA consists of a review of component, assembly, and system design characteristics in terms of their vulnerability, and indicates the most likely effect in the light of possible failures. As the study is performed by reliability and design engineering, recognition of sources of degradation incurred during the Product Fabrication Regime is almost nil. There is a need to identify process, assembly, inspection and test problems that may compromise system reliability during field deployment, in addition to those areas that are influenced by engineering design.

5. Burn-in, as depicted in Figure 1 indicates that useful product life starts with its completion, followed by customer acceptance. Its purpose is to surface sources of infant mortality prior to customer delivery. Premature failures after customer receipt raises questions as to the sufficiency and effectiveness of burn-in. The presence of latent defects that become obvious only after time and use indicates the need for more effective screens during the Product Fabrication Regime. Field failure data should be fed back to augment the FMEA, and provide guidance as to where additional screening can be most effective.

A brief insight has been presented into the Quality aspects of the product life cycle. The omission of these factors may account for part of the difference between predicted and operational reliability. The "parts count," failure rate prediction, except for such relatively few considerations as the failure rate for connections, PC boards and a "quality factor," π applied to failure rates, infers through omission of the manufacturing function that it has negligible influence on achieved reliability. The impact of rework and repair, particularly when catastrophically failed components may cause secondary overstress, is generally neglected for MTBF predictions. It is not reasonable to expect an assembly that has been repaired a number of times to exhibit the same reliability as an undisturbed assembly.

The tacit reliance on downstream assembly, system test and inspection to screen defectives places an excessive demand on these functions, increasing the probability of higher order defect escapes due to imperfections in these operations. The initial quality conditions caused by manufacturing variability must be included in reliability predictions, to complement the parts count -- failure rate methodology.

With the ever increasing emphasis on product liability, and the military now focusing on Reliability Improvement Warranty (RIW), the successful evolution of a product must, of necessity, be considered from the viewpoint of Product Assurance, rather than the heretofore separate entities of Quality and Reliability.

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VENDOR QUALITY ASSURANCE AND RELIABILITY

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In today's highly competitive home entertainment electronics market, the name of the game as far as the end customer is concerned is a more reliable product at a lesser cost.

It becomes an ever increasing search on the part of the producer to meet the challenges of higher quality and reliability demanded by today's customers while still holding the cost down.

The first question, of course, is what do these demands do to the vendor cost and what does this do to the profit picture of the Corporation. For as we all know, any company, to stay in business, must realize a reasonable profit.

One of the most fertile areas in which to work to meet the demands of higher quality and reliability is in the product or component as received from the vendor. Over the years, it has been common practice that when a manufacturer purchased a component, he would inspect it to insure that it conformed to the print and/or specification before placing the item into his production facilities.

If the component has been properly designed by the manufacturer's Engineering Department, and the parameters and tolerances are realistic for the end quality and reliability desired, he should not have to inspect the item as received if both the vendor and the manufacturer have firm understanding of what is desired.

Zenith has a program which is known as the Zenith "Vendor Quality Assurance Reliability Program". It is the purpose of this Program to work closely with Design Engineering, Purchasing, Manufacturing, and the vendor in welding a team which would have the same end objectives and offer benefits to both Zenith and its vendors.

It was decided that the classification of defects and the quality levels for our Program would be 0% for critical which is safety related defects, and .65% for majors and 1% for minors.

The first step in the Vendor Quality Assurance Program is that of qualification to determine if the vendor is qualified to produce the component per the print and/or specification set forth by Design Engineering. For it is our belief that unless the vendor is qualified; that is, he has the proper facilities, test equipment, technical capabilities, expertise, he will not consistently produce the component to the quality and reliability demanded by Zenith.

The Zenith Vendor Quality Assurance Program works as follows: To introduce a vendor to the Program, the Zenith Purchasing Manager extends an invitation to the representatives of the vendor's Management, Quality Control, Marketing and Manufacturing to visit Zenith and meet with the Purchasing Manager, a Vendor Quality Assurance Engineer, and a Design Engineer. At this meeting, the Vendor Program is explained by a visual, oral slide presentation, pointing out the benefits that can be received by both the vendor and Zenith. As our program progressed and to reach more vendors in a shorter period of time, we held group vendor meetings consisting of 15 to 20 vendors at a time.

The first thing explained at this meeting is the Zenith AQL levels and classification of defects. We require our vendors to certify to 0% for critical failures (safety related parameters) and .65% for major defects and 1% for minors. Following this explanation, the vendors are given a series of questionnaires and requested to fill these out so that we may have a record of his facilities and equipment. These questionnaires are designed so as to have the vendor show the type of equipment he has, its accuracy and whether the equipment is used in Production, Engineering, or in Environmental type setups. Also it is explained to him at this meeting that once he is qualified, a Correlation Program will take place wherein he will measure a given

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number of components he manufactures for Zenith, recording the exact data for the parameters agreed upon and then the data and measured components are submitted to the Zenith Incoming Quality Control Department at the using plant for their evaluation and correlation of the data.

Once correlation is established, the vendor is requested to periodically submit correlation samples with appropriate data in with incoming shipments so that a continuous correlation can be maintained.

Following correlation, the vendor is requested to supply certification sheets with each incoming shipment. This is not merely a letter stating that the vendor certifies the shipment per the Zenith print and/or specification, it should be a copy of his outgoing quality inspection showing the number of samples taken and the number of defects found for each parameter measured and the AQL levels to which he inspects.

Following this meeting, the vendor is informed that when we receive the completed questionnaires, and they are reviewed and found to be complete, an appointment will be made for a Zenith Survey Team; consisting of: Purchasing, Design Engineering, when required, and Vendor Quality Assurance to visit his facilities. It is the objective of this Survey Team to meet with the vendor's top personnel from such departments as: Management, Marketing, Production, Purchasing, Quality Control and Engineering to again explain the entire Zenith Vendor Quality Assurance Program and the Zenith AQL levels and classification of defects.

After this meeting, the vendor's personnel and the Survey Team tour the vendor's facilities in order to assure themselves that the vendor is capable of manufacturing a component with good reliability and high quality to the Zenith print and/or specification. Following the tour, again a meeting is held with the vendor's top personnel so that any questions on either the part of the Survey Team or the vendor, may be answered. The Survey Team requests from the vendor once each month a copy of his monthly Environmental Test data and/or life test results. In a business such as Zenith is engaged in, if our Environmental Test Lab were ten times its present size, we could not possibly environmentally check every component every month. However, since the vendor is doing this as a continuous control within his facilities, we have found him to be most happy to supply us with carbon copies of his results. This gives us an additional control in our Program.

If the Survey Team is satisfied that the vendor is capable of meeting the requirements of the Zenith Vendor Quality Assurance Program, they request a letter from an officer of the company, stating that he, the vendor, is in agreement with the Program and will work with Zenith in making the Program a success.

The correlation part of the Program is put into effect following this meeting and as soon as correlation is completed, the vendor starts to certify his incoming shipments. Attached is a copy of the questionnaires used, letters mailed to the vendors along with samples of correlation sheets and suggested certification sheets. This Program has been so designed as to be flexible in the area of obtaining needed data. We have found that if we would demand of the vendor that he record data on specific data sheets, we would most assuredly increase the cost of the component received by Zenith. Therefore, we are always open to using the vendor's data sheets if it is complete and gives the information desired. However, in many cases if the vendor does not have adequate data sheets, he is most anxious to accept the one suggested by Zenith.

One area which we have found to be extremely important in this Program is that of lot numbering or identifying each incoming shipment. The vendor either starts a lot numbering system or in many cases, he has been able to use his Shop Order number as a lot number and this gives an excellent control since we can trace it back to when the job started. The only restriction to the lot number is that it must not repeat itself in less than 18 months.

The real importance of the lot number to Zenith is that when a quality problem is found in Production, we are able to trace it and not have to go through all the material in our house. Again, it gives us an excellent control in this Program and a means of tracing information between the vendor and Zenith.

Now that the vendor has been qualified, and correlation is established, he is ready to enter into the certification of incoming shipments. As was explained earlier, his incoming shipments must be accompanied with a copy of his outgoing quality control sheet showing the amount of samples taken and rejects found. This sheet should be signed by the Quality Control Manager of the company. This then becomes the certification document. The first five shipments received at Zenith are inspected in our normal incoming inspection procedure which uses MIL STD. 105D Level II. If we find the first five shipments to meet our AQL's and the data sheets to be complete, we then certify the vendor for that particular part number only. Here, I would like to point out that we certify our vendors by PART NUMBER. We qualify a source but we correlate and certify by part number only. Following these first five shipments, Incoming Inspection then has the prerogative of inspecting any one out of the next five shipments providing each shipment has an adequate data sheet accompanying it. However, Incoming Inspection at Zenith is NOT permitted to skip lot any "safety related parameters". All safety related parameters must be inspected without exception. The shipment to be inspected is selected at random, usually by throwing a die and in this manner, the vendors have no idea as to which shipment will be inspected. However, Zenith, of course, has the prerogative of inspecting each shipment as it is received on either a full or a sampling basis.

A vendor continues in the manner described above until a quality problem is found either by Incoming Inspection in the inspecting of one of the lots or if a latent quality or reliability problem is found in the production lines on a shipment which was passed under certification. When this condition arises, the vendor is removed from certification, notified of the quality problem, and all incoming shipments are inspected using MIL STD. 105D Level II.

Now, for him to be recertified, he must first submit documentary proof that he has corrected the problem and again, we must receive five consecutive shipments which will be inspected under the normal sampling plan of MIL STD. 105D Level II without rejection along with complete certification sheets. If all goes well with these five shipments, he will again become certified for that part number.

We here at Zenith have a group of graduate Engineers known as Vendor Quality Assurance. It is the responsibility of this group of Engineers to work with the vendors in establishing of the Zenith Vendor Quality Assurance Program in their plants and to work closely with vendors when quality problems arise. So, when a vendor is removed from certification, one of these Engineers works with him in the elimination of the problem and assists him in becoming recertified.

This is the explanation of the way Zenith works in the control of their vendor's quality. However, we feel that any Program such as this must have certain benefits for both parties concerned for it to be a success. Some of the benefits which we have noted are:

- A. Improved quality.
- B. Improved reliability.
- C. Faster approvals.
- D. Fewer rejections.
- E. Saving of environmental test time.
- F. Better assurance of the vendor's quality.
- G. Vendor better informed of what is expected of him and his product.
- H. Through the reporting of control dimensions, he will know where to concentrate his inspection to a minimum while still assuring component of the desired quality and reliability required by the Engineering specification.
- I. Shipping cost savings can be realized by the assurance of quality and acceptance of his material.
- J. Rework and scrap costs will be minimized.
- K. By the use of recognized quality control techniques, he will have reliable records of his quality.

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L. Better vendor-Zenith relations.

K. Zenith benefits by: The assurance of better incoming quality and reliability, better quality of our manufactured product and increased sales which is also a vendor benefit.

In addition to these, it is our feeling that every program such as this should have some incentive to arouse the interest of the vendor's people in the Program. As a result, Zenith initiated a Vendor Quality Certification Award. This award is a means of informing the vendor and his personnel that they are doing a good conscientious quality job for Zenith and the Vendor Quality Assurance Program. The award is presented twice per year in January and July. The award is signed by our Vice President of Manufacturing, Vice President of Purchasing Department, Executive Director of Purchasing, Director of Corporate Quality Control, Director of Incoming Quality Control, and Manager of Vendor Quality Assurance.

The program works as follows:

VENDOR PERFORMANCE RECOGNITION AWARD PROGRAM

Purpose

The Vendor Recognition Award Program is designed to recognize those vendors who deliver material of above average quality to Zenith Radio Corporation over an extended period of time. The two levels of awards are intended to motivate above average (B) vendors to attain an excellent (A) rating.

Eligibility

1. The vendor must have been an active Zenith vendor for more than one year.
2. The vendor must have delivered at least 6 lots of productive material to Zenith during the six month rating period.
3. The vendor must be in compliance with the Zenith Radio Corporation Vendor Quality Assurance/Reliability Program.
4. The vendor must not have had any major in-process quality or reliability problems which were due to vendor responsible failures in the product during the award period.

Awards

1. A "Gold" Recognition Award will be presented to those vendors who have a rating of A for all parts supplied as reported by all Zenith IQC Departments during a given award period via the Vendor Analysis System. The requirements for an A rating are as shown below.
2. A "Green" Recognition Award will be presented to those vendors who have an overall rating of A but have some specific parts with B ratings as reported by all Zenith IQC Departments during a given award period via the Vendor Analysis System.

Note: An A vendor rating is obtained by having a performance figure of 1% or less based on the following formula.

$$\text{Vendor Rating} = \frac{\text{Lot Rejection Percentage} + 4 (\text{Process Average})}{5}$$

$$\text{Process Average } (\bar{P}) = \frac{\text{AA defects} + \text{A defects}}{\text{Total Samples}}$$

Procedure

1. At the end of June and December of each year, the Vendor Quality Assurance Department will get an overall performance rating for all Zenith vendors.
2. These overall ratings will be reviewed per the above eligibility rules and a list of eligible vendors will be formulated.
3. The list of eligible vendors will be reviewed by the Vendor Quality Assurance Engineers to be sure that Zenith is not having in-process or reliability problems with any of the eligible vendors' products.

4. The award eligibility list will then be submitted to the Purchasing Managers for their review and approval.
5. The list of eligible vendors will then be returned to Vendor Quality Assurance and the appropriate award will be generated.
6. Awards will be presented at Zenith and/or vendor's facility as appropriate within 30 work days after the close of the rating period (six months).

We also have a "Zenith Computerized Vendor Rating Program" which is so designed as to supply to our vendors a monthly computer report which shows his quality performance as seen by Incoming Quality Control (incoming inspection) Departments.

The Program operates as follows.

ZENITH COMPUTERIZED VENDOR RATING PROGRAM

Once each month our vendors will receive in the mail a copy of the "Zenith Radio Corporation Vendor Performance Report". This report will show by part number the quality status of the materials shipped by the vendor to our Zenith facility for the previous month.

Attached is an example of the report the vendor will be receiving and reads as follows.

Item A - Company name and Zenith vendor number.

Item B - The part number(s) vendor has shipped to a Zenith facility in the previous month.

Item C - Week ending, designates time period in which material was received and inspected.

Item D - Shows number of lots inspected, number of lots rejected, percent rejected and the number of rejected lots returned to the vendor. If there is a difference between the number of lots rejected and the number of lots returned to the vendor, this would mean Zenith elected to use these lots by 100% sorting, reworking, or by deviation.

In any of these cases, the vendor would have been notified by the Vendor Quality Control Engineer as to our decision and the action taken to use the material in production.

Item E - Shows number of parts received and number of parts rejected.

Item F - Shows number of random samples taken per MIL-STD-105D Level II single sampling, from the lots inspected (reference Item D).

Item G - Shows total defects found in the samples inspected. The three classes of defects shown are:

"AA" - Critical or safety related.

"B" - Major defect.

"C" - Minor defect.

Item H - Shows the process average for the total samples inspected. The process average is established by means of the following formula.

$$\text{Process Average} = \frac{\text{"AA"} + \text{"A"}}{\text{Total Samples}}$$

Item I - Shows approval status for components vendors ship to Zenith:

- A - Approved.
- L - Limited Approval.
- N - Not Approved.
- W - Approval Withdrawn.

Item J - Shows Vendor Rating Code.

- A - Excellent.
- B - Good.
- C - Average.
- D - Poor.
- E - Unsatisfactory.

This then is the basics on which Zenith Vendor Quality Assurance Program operates.

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ZENITH RADIO CORPORATION
CORPORATE QUALITY CONTROL
VENDOR QUALITY/RELIABILITY EVALUATION REPORT

DATE
PREPARED BY

COMPANY NAME	DIVISION OF		
STREET ADDRESS	CITY	STATE	PHONE NO.
TYPE OF PRODUCT MADE			

QUALITY ASSURANCE

DO YOU HAVE A QUALITY CONTROL DEPARTMENT?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
DO YOU HAVE A QUALITY ASSURANCE DEPARTMENT?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
IF SO, TO WHOM DO THEY REPORT?		
HOW DO THEY RELATE?		
IS THE RELIABILITY FUNCTION		
<input type="checkbox"/> SEPARATE OR <input type="checkbox"/> COMBINED		
DO YOU HAVE A WRITTEN QC/QA RELIABILITY PROGRAM?		
<input type="checkbox"/> YES <input type="checkbox"/> NO		
<input type="checkbox"/> ATTACH TO THIS REPORT, IF AVAILABLE, AN OVERALL COMPANY QUALITY ORGANIZATION CHART.		
<input type="checkbox"/> ATTACH TO THIS REPORT, IF AVAILABLE, A Q.C. AND/OR Q.A. MANUAL.		
HAS THIS MANUAL BEEN COORDINATED WITH ANY GOVERNMENT AGENCIES?		
<input type="checkbox"/> YES <input type="checkbox"/> NO		

INSPECTION CAPABILITIES

DO YOU HAVE A FORMAL INCOMING INSPECTION FUNCTION?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
IF SO, TO WHOM DO THEY REPORT?		
WHAT TYPES OF RECORDS ARE KEPT OF BOTH ACCEPTED AND REJECTED MATERIALS?		
DO THEY HAVE AVAILABLE ALL SPECIFICATIONS AND DRAWINGS PERTAINING TO THE RECEIVED MATERIAL?		
<input type="checkbox"/> YES <input type="checkbox"/> NO		
IS THERE AN IN-PROCESS INSPECTION PROGRAM?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
IS THERE A FINAL INSPECTION PROGRAM?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
IS THIS INSPECTION ROUTINELY MONITORED BY Q.A.?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
WHO PROVIDES SAMPLING PLANS AND TEST PROCEDURES?		
IS THERE A FINAL INSPECTION OF PRODUCT?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
DOES FINAL Q.A. USE A SAMPLING PLAN?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
WHAT AQL'S ARE EMPLOYED?		
ARE THERE ADEQUATE RECORDS OF INSPECTION RESULTS?		
<input type="checkbox"/> YES <input type="checkbox"/> NO		
WHAT PRECAUTIONS ARE USED TO ASSURE PROPER ENVIRONMENTAL CONTROL OF RECEIVED MATERIALS?		
ARE THEY MAINTAINED WHEN MATERIAL IS RELEASED TO PRODUCTION?		

VENDOR

1 OF _____

SAMPLING PLAN	AQL'S MAJOR _____ % MINOR _____ %
SAMPLE SIZE(S)	ACCEPTANCE NOS. MAJOR _____ MINOR _____

[illegible]

REMARKS:

DATE _____

Quality Award



hereby presents to:

This award in recognition of outstanding Product Quality supplied
to Zenith during the period of _____ to _____,
subject to all standards, procedures and provisions of

the Zenith C.R.:100 Program.

Mgr. Vendor QA

Otto W. Lemke

Director
Corp. Quality Control

Mr. Corporate QC
Incoming Material

J. F. Frazier

V.P. Manufacturing

Exc. Dir. Purchasing

John Macpherson

V.P. Material

REPORT NO. 71504

ZENITH RADIO CORPORATION VENDOR PERFORMANCE REPORT

PAGE NO. 1

BY VENDOR BY PART NUMBER

A	B	C	WEEK ENDING	D			E	F	G	H	I	J			
				WEEK ENDING 7/04/75											
VENDOR NAME NUMBER	PART NUMBER	WEEK ENDING	NUMBER OF LOTS-----			TOTAL SAMPLE	TOTAL REJECTED	TOTAL DEFECTS----			APP. STAT	VR CDE			
			INSP.	REJ	% RTV			AA	A	B					
ABC COMPANY 123456	S-85229-01	7/04/75	101	7	6.9	5	875,653	2,441	1,239	0	19	123	4.0	A	C
		6/20/75	91	1	1.1	1	793,397	1,493	1,122	0	8	29	1.3	A	B
		6/06/75	97	0	0	0	801,233	0	1,150	0	0	0	0	A	A
	063-01792	7/04/75	90	3	3.3	0	1,987,654	98,765	1,987	0	84	66	5.7	A	C
		6/20/75	76	1	1.3	1	8,231,545	8,233	3,500	0	16	4	0.5	A	A
		6/06/75	51	0	0	0	22,333	0	630	0	1	4	0.3	A	A
	063-01899	7/04/75	18	16	88.9	16	54,200	49,100	1,675	0	575	15	34.6	W	E
		6/20/75	9	1	11.1	1	30,150	2,600	995	0	17	29	2.4	A	C
		6/06/75	11	1	9.1	0	33,250	3,305	1,055	0	9	14	1.2	A	B
	063-09921-10	7/04/75	9	0	0	1	123,456	2,345	950	0	16	24	2.3	A	B
		6/20/75	5	0	0	0	12,345	1,234	670	0	9	18	2.1	A	B
		6/06/75	0	0	0	0	0	0	0	0	0	0	0	L	
	063-09921-80	6/20/75	136	18	13.2	11	1,167,293	321,443	1,229	0	42	57	4.6	A	C
		6/06/75	8	1	12.5	1	93,875	2,307	873	0	76	101	11.6	A	E
TOTAL		7/04/75	218	26	11.9	22	3,040,963	152,651	5,851	0	694	228	12.8		E
		6/20/75	321	21	6.5	13	10,234,730	335,003	7,516	0	92	137	1.7	B	B
		6/06/75	167	2	1.2	1	950,691	5,612	3,708	0	86	119	3.1		B

---END OF REPORT---

A DEFECT REPORTING SYSTEM OF HONEYWELL

Joseph P. Hodge, Quality Supervisor
Honeywell Avionics Division
St. Louis Park, Minnesota 55416

An effective quality organization ascertains defects or failures and their trends in a timely manner. Honeywell accomplishes this by a responsive reporting system and data base used by all disciplines throughout all phases of production build and test. This paper describes Honeywell's system used during build and test of electronic hardware.

HONEYWELL DEFECT REPORTING SYSTEM

The Honeywell Defect Report (HDR), Figure 1, is the basic system document. It is initiated by both production and inspection personnel when any defect or failure is observed during functional testing at all levels of assembly, including final device build level. The HDR form is also used for return goods evaluation and subsequent repair. When an anomaly is observed, the technician performing the test enters the description of the defect, the test during which the defect was noted, the environment (high, low, or room temperature), and the data on the HDR. When the cause of the anomaly is found, the technician performing the analysis and troubleshooting completes the HDR. He includes such information as cause of defect, rework action required, and any recommended preventive action. He also lists the circuit location and part numbers of all components replaced and the reasons for replacement.

The completed HDR is now separated; it is a three part form. The first copy along with defective components (attached) are sent to the responsible program Quality Engineer, the second copy is sent to the Production Foreman, and the third copy remains in the device folder as a permanent record. Figure 2 shows the flow of the HDR system and the responsibilities of each discipline in the total system.

The Production Foreman reviews his copy of the HDR for adverse trends, operator performance problems, and completeness. His review could result in a number of actions --

- Retraining/recertification of an operator
- Re-assignment of an operator
- Disciplinary action
- Request for engineering analysis of a process problem
- Request for engineering change to existing procedures

The Production Foreman's review is important because he takes timely action on workmanship problems or requests engineering assistance on more complex problems.

The Quality Engineer, upon receipt of his copy of the HDR, discerns obvious adverse trends, process problems, and operator performance problems. To aid him in performing this function, a computer program has been established that processes information coded by the Quality Engineer from the HDR forms. An example computer printout is given in Figure 3. This program is run weekly and is distributed to cognizant Production, Reliability, and Design Engineers for review. Also, upon request, a run can be made to cover any time frame desired (month, year, program inception to date) for trending purposes.

In reviewing the run, information such as program, device serial number, major assembly, minor assembly, failed part, date, test level (where anomaly occurred), cause, circuit location, and HDR number are listed. Also the run can be sorted by any of the above elements. The example (Figure 3) is sorted by program, failed part, and circuit location. This computer program has been extremely valuable in identifying recurring failures due to lot-related piece part defects, process problems, circuit application problems, and recurring workmanship defects.

The Quality Engineer works primarily with Reliability, Production and Design Engineers, the Production Foreman, Inspection Foreman, and Procurement Quality Assurance in resolving problem areas and obtaining expeditious and effective corrective action. Some typical actions that can result are:

- Print changes
- Process changes
- Work instruction changes
- Additional operator training
- Vendor corrective action
- Field retrofit
- Continued monitoring for additional trend

FAILURE REPORTING ANALYSIS AND CORRECTIVE ACTION SYSTEM (FRACA)

The FRACA system, which is used in conjunction with the HDR system, is a closed-loop, documented corrective action system. A Failure Analysis Committee (FAC) comprised of members from Quality, Reliability, Design, and Production Engineering implement the system. When a potential trend problem is detected, formal failure analysis is performed isolating the cause of the failure and defining the necessary corrective action. This analysis and corrective action is documented, with concurrence required from all engineer disciplines on the FAC. Quality Engineering ensures implementation of the corrective action and monitors the effectiveness of this action through the HDR system. In a review by a special NAVAIR-Reliability audit team in 1976, Honeywell was commended on having one of the best reporting and corrective action systems in industry.

SALVAGE MONITORING

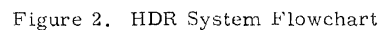
Coupled with the HDR system, a computer program has also been established by Quality that provides, on a weekly basis, information on production salvage time expended during replacement of defective piece part components during all phases of the manufacturing process. Analysis has shown that the greatest amount of piece part salvage expended is limited to particular families of components, and Pareto's Principle of Maldistribution can be used to organize salvage information. This information aids in identifying high cost areas where corrective action is required and also aids in evaluating the effectiveness of previous corrective actions. Figure 4a is an example summary sheet, and Figure 4b is an example trend sheet for integrated circuits used on a specific program.

SUMMARY

Honeywell's Defect Reporting System is a key element of our quality program. It is important not only in controlling salvage and scrap cost but has been vital in meeting field performance criteria, thus avoiding costly retrofit and/or loss of future business because of poor performance. Through its conscientious use, it summarizes and identifies problem areas that can be monitored easily and continually.

FD-204 (REV. 1-73)

SHEET 127321 OF 127321



SALVAGE SUMMARY

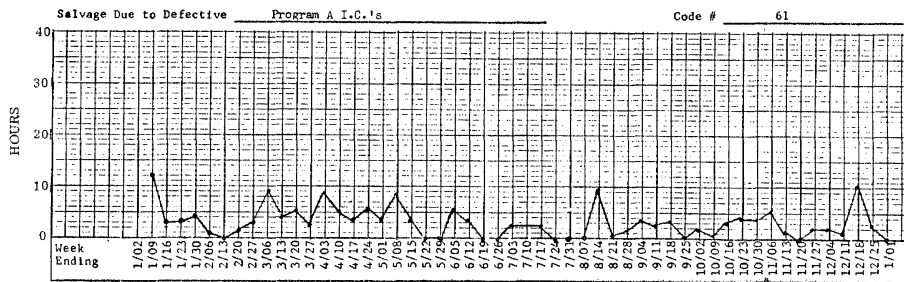
Component Piece Parts

For Week Ending <u>January 1, 1978</u>	Year-to-Date Total
Component Salvage Hours <u>113.0</u>	Component Salvage Hours <u>5323.6</u>
Total Salvage Hours <u>300.9</u>	

PROGRAM	WEEKLY HOURS OF COMP. SALVAGE	PERCENT OF TOTAL COMP. SALVAGE	Y-T-D HOURS OF COMP. SALVAGE	PERCENT OF TOTAL COMP. SALVAGE
A	<u>28.2</u>	<u>25.0 %</u>	<u>2719.7</u>	<u>51.0 %</u>
B	<u>9.3</u>	<u>8.2 %</u>	<u>471.3</u>	<u>8.9 %</u>
C	<u>34.2</u>	<u>30.3 %</u>	<u>1583.8</u>	<u>29.8 %</u>
D	<u>7.2</u>	<u>6.4 %</u>	<u>65.9</u>	<u>1.2 %</u>
E	<u>.5</u>	<u>.4 %</u>	<u>127.8</u>	<u>2.4 %</u>
F	<u>13.3</u>	<u>11.8 %</u>	<u>279.2</u>	<u>5.2 %</u>

<u>A</u> <u>Component</u> <u>Hrs. Salvage</u> Diode 10.6 Capacitor 8.7 Transformer 3.2 22.5 The above components accounted for 80% of Program A Salvage	<u>B</u> <u>Component</u> <u>Hrs. Salvage</u> Transistor 4.3 Transformer 2.5 Diode 2.0 8.8 The above components accounted for 95% of Program B Salvage	<u>C</u> <u>Component</u> <u>Hrs. Salvage</u> Int Ckt 10.6 Resistor 7.7 Purchase Components 4.5 Transformer 4.0 RF Head 4.0 Diode 3.0 33.8 The above components accounted for 99% of Program C Salvage
<u>D</u> <u>Component</u> <u>Hrs. Salvage</u> Capacitor 4.8 Resistor 2.0 6.8 The above components accounted for 94% of Program D Salvage	<u>F</u> <u>Component</u> <u>Hrs. Salvage</u> Cavities 3.2 Int Ckt 2.4 Capacitor 2.3 7.9 The above components accounted for 59% of Program F Salvage	

Figure 4a. Sample Salvage Monitoring Summary Sheet



LCS 730:70:436 Figure 4b. Sample Salvage Monitoring Trend Sheet

Wayne Tustin, President
Tustin Institute of Technology
Santa Barbara, California

INTRODUCTION

This paper primarily affects quality and reliability organizations within the Navy and Air Force and within firms building (1) avionics equipments for use in jet aircraft and (2) airborne missiles, weapons and assembled external stores carried by jet aircraft. These organizations are strongly impacted by the random vibration requirements of the October 1977-released *Military Standard 781C*⁽¹⁾. Quality and reliability personnel in other services and other firms should also be aware of random vibration. Their equipments, in transit and use, may experience little or no random vibration, but random vibration effectively screens against certain types of workmanship flaws.

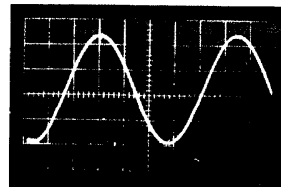
This paper does not deal with the reliability nor the statistical aspects of the *Standard*. It largely ignores the varying temperature and the humidities required for tests under -781C, also the sinusoidal tests required for fixed ground equipments and for equipments destined for transport and use aboard ground vehicles, ships, helicopters and turboprop aircraft.

Rather, this paper emphasizes the random vibration tests which -781C requires for reliability demonstration tests of avionics elements of jet-powered fighter aircraft, transports and bombers, also tests of air-launched weapons and external equipments.

Certain figures and tables of -781C and other standards are reproduced here; they carry the numbering of those documents. Figures in this paper carry letters from A through C and the paper provides cross references to those documents.

WHAT IS RANDOM VIBRATION?

Let us first consider sinusoidal vibration and Figure A, in which the sinusoid represents a time history, a record of instantaneous acceleration varying sinusoidally with time. The lower portion of Figure A is the corresponding spectrum; it shows that all the vibratory energy is concentrated at a single frequency f . For some tests, f is fixed. For other tests, f varies according to some program. Such tests generally only excite one specimen resonance at a time.



Sinusoidal vibration is seldom found in the real world, and sinusoidal vibration tests are likely to be inappropriate representations of the transportation and use environments. However, they may be appropriate for equipments going into fixed ground installations, on board ships and helicopters.

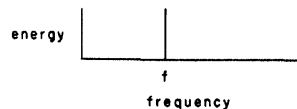
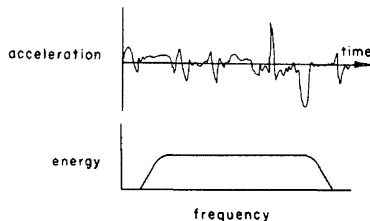


FIGURE A
Sinusoidal Vibration



By contrast, consider Figure B, in which the time history represents acceleration varying randomly with time. The corresponding spectrum shows that vibratory energy is spread out over a continuum, a continuous range of test frequencies. The principle advantage of random vibration testing is that all specimen resonance are excited simultaneously, much as occurs aboard high-performance aircraft and missiles in flight.

FIGURE B
Random Vibration

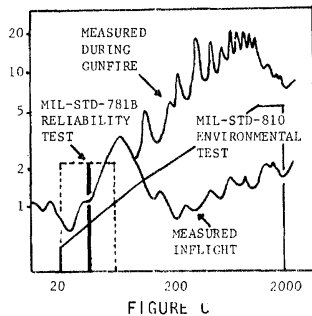


FIGURE C
Vibration of forward-looking radar on A-7D/E aircraft, RMS g vs. frequency in Hz

What was wrong with the vibration tests required under MIL-STD-781, -A and -B? As suggested by Figure C, taken from Swett⁽²⁾, vibration (combined with varying temperature) at an intensity of 2.2g was applied at any optional fixed nonresonant (nondamaging) frequency between 20 and 60 Hz. Not surprisingly, test vibration-induced failures have been rare, even with long-duration tests. But in-flight vibration aboard high-performance aircraft and free-flying missiles, also aboard captive-carried external weapons and stores, is known to relatively quickly induce failures. Why the discrepancy? Figure 6 shows that in-flight vibration and gunfire-induced vibration are broadband. The environmental broad-spectrum random vibration qualification tests exemplified by MIL-STD-810⁽³⁾ are more realistic for this application; such spectra are more useful for reliability demonstration tests than was the original -781.

In addition to greater test realism, random vibration testing has been shown⁽⁴⁾ to be more effective than sinusoidal vibration for screening. Workmanship errors such as poorly soldered electrical connections, loose screws, scraps of wire, etc. are quickly identified.

Figure 1 of the *Standard* shows that vibration and equipment power are to be switched on and off, while temperature and supply voltage are to be varied. Sufficient moisture should be provided to give visible condensation, frosting or freezing depending upon temperature.

TEST CONDITIONS/LEVELS

Hopefully, the combinations of environmental test conditions and levels applied under this *Standard* will fairly represent field and use conditions. Section 4.3 lists preferences: (1) test conditions and levels should be based upon measured stress and levels at proposed equipment locations during typical missions. Failing that, (2) estimates may be based upon measured environmental data from similar applications. Only (3) when stresses are not specified, or when measured stresses or estimates are not available, should test personnel use the stress types and levels found in Appendix B of the *Standard*. The random vibration aspects of Appendix B will be discussed later.

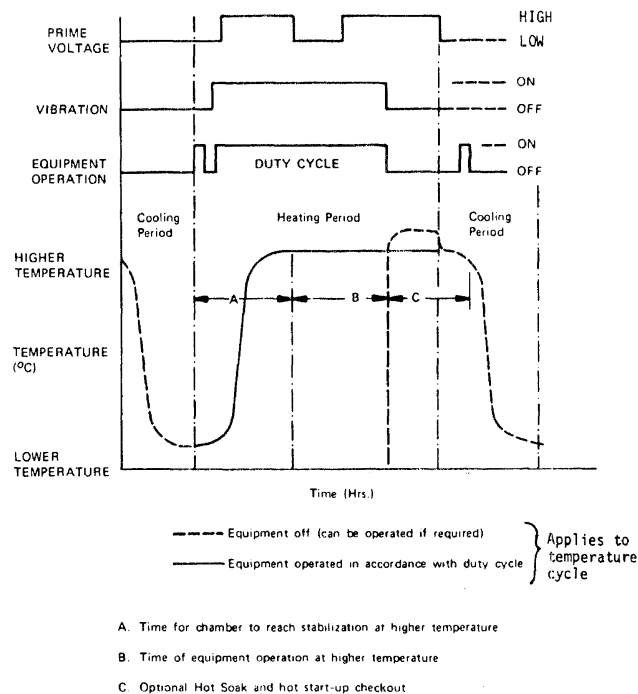


FIGURE 1 from MIL-STD-781C
Sample Environmental Test Cycle

COMBINED ENVIRONMENTAL CONDITIONS/STRESSES

Further, Section 4.3 requires that the stresses of varying voltage, vibration, equipment on/off and variations of temperature are to be combined in the same chamber per Figure 1 (on the previous page) and Table I (of which only the aircraft requirements are reproduced below).

Table I. Summary of Combined Environmental Test Condition Requirements

	AIRCRAFT				AIR-LAUNCHED WEAPONS AND ASSEMBLED EXTERNAL STORES
	FIGHTER	TRANSPORT, BOMBER	HELICOPTER	TURBO-PROP	
ELECTRICAL STRESS					
Input voltage range	nominal $\pm 10\%$	$\pm 10\%$	$\pm 10\%$	$\pm 10\%$	$\pm 10\%$
Voltage cycle	(nominal, high and low voltage, one cycle/thermal cycle or per APPENDIX B)				
VIBRATION STRESS					
Type vibration	random	random	swept-sine log sweep	swept-sine	swept-sine*** and random
Amplitude	(SEE APPENDIX B)	SEE APPENDIX B	SEE APPENDIX B	SEE APPENDIX B	SEE APPENDIX B
Frequency range	20-2000 Hz continuous	20-2000 Hz continuous	15-2000 Hz sweep rate 15 min. one/hr	10-2000 Hz continuous (see APPENDIX B)	20-2000 Hz continuous (see MIL-STD-1670)
Application	LOW HIGH	LOW HIGH	LOW HIGH	LOW HIGH	LOW HIGH
THERMAL STRESS (°C)					
Storage temperature (non-oper.)	-54 +71	-54 +71	-54 +71	-54 +71	-65 +71
Operating temperature range	(SEE APPENDIX B)	(SEE APPENDIX B)	(SEE APPENDIX B)	(SEE APPENDIX B)	(SEE APPENDIX B)
Rate of change (min.)	5°/min. 3 1/2 hours	5°/min. 3 1/2 hours	5°/min. 3 1/2 hours	5°/min. 3 1/2 hours	5°/min. 3 1/2 hours
Duration (nominal)	(1/test cycle)	(1/test cycle)	(1/test cycle)	(1/test cycle)	(1/test cycle)
MOISTURE STRESS					
Condensation					
Frost/freeze					

*** Frequency tolerance ± 2 percent or ± 5 Hz for frequencies below 25 Hz.
 ***** See 50.5.3 of Appendix B.

OPTIONAL NON-STATISTICAL SEQUENTIAL TEST

Section 4.4 of the *Standard*, however, offers options of sequential vibration, temperature cycling and moisture, if approved by the procuring agency. Option I includes 10 minutes of single-axis random vibration per Figure 2 (see next page of this paper) with power applied. (The ordinate should be acceleration spectral density.) Option II permits, instead, "broadband/complex" vibration; this term appears to have been included to permit the use of certain recent mechanical and pneumatic shakers whose spectra are collections of lines (as opposed to the continuous spectra attainable with electromagnetic and electrohydraulic shakers to meet Figure 2 for example.)

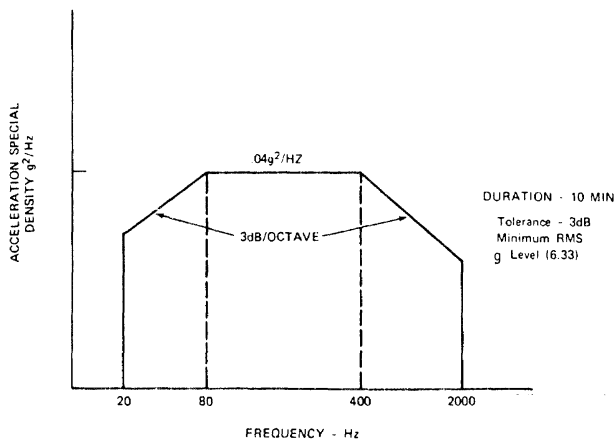


FIGURE 2
Random Vibration Acceptance Test

RANDOM VIBRATION NEEDED

To quote Section 4.3.2.2 from the *Standard* concerning Vibration Stress, ".....The intent.....is to produce, in the equipment on test, a vibration response with a character, magnitude, frequency range and duration similar to that produced by the field service environment and mission profile....."

Certain modes of vibration-induced failure, found in flight (particularly aboard jet aircraft, missiles and external weapons), also in random vibration testing, seldom if ever appear with sinusoidal vibration testing. Combining random vibration with other stresses, as in -781C, gives

highly encouraging test results. Laboratory failure modes tend to closely resemble in-flight failure modes. Laboratory mean times between failure (MTBF's) tend to closely approximate in-service MTBF's. Among the kinds of failure that appear are those due to poorly-soldered connections, due to loose scraps of wire, due to loose screws, etc. A major value of random vibration testing is screening against such defects.

However, during 1975 and 1976 several drafts of -781C drew strong negative responses from some contractor firms which had been happily performing reliability demonstration tests according to the earlier issues. The need to invest in new shaker systems unfortunately requires vast capital outlays, more highly trained and motivated test personnel and other expenses. Hence those firms have been greatly interested in low-cost mechanical and pneumatic shakers (5, 6, 7).

Some contractors remember unhappy experiences with early random vibration testing systems which were expensive to purchase, difficult to operate and highly unreliable. Fortunately, certain shaker system improvements 1970-1976 contributed greatly to ease of operation and to shaker system reliability. Chief among these were:

- More rugged electromagnetic shakers,
- Solid-state power amplifiers, and
- Solid-state, digital controls.

Still, for many firms and agencies, random vibration testing on electromagnetic or electrohydraulic shakers is formidably expensive.

Environmental testing laboratories can reproduce in-service vibration using magnetic tape recorded in service. This practice is used extensively in road simulation tests of autos and trucks. However, aircraft and missile environmental testing laboratories generally synthesize random vibration using noise generators, limiters, equalizers and a host of other analog or digital controls.

TYPES OF SHAKERS

The low frequency (generally below 60 Hz) sinusoidal vibration needed for fixed ground equipment and for shipboard equipment has long been supplied by inexpensive, reliable, easy-to-operate mechanical shakers. Higher frequency sinusoidal vibration tests for ground vehicles, helicopters and turboprop aircraft, as well as random vibration tests for fighters, jet transports, jet bombers and for air-launched weapons and external stores, necessitate expensive and complex shakers and controls. Electromagnetic shakers are most widely used in the frequency range (to 2,000 Hz) needed for avionics and weapons tests. However, electrohydraulic shakers are increasingly favored for low-frequency, long-stroke, high-force applications. Multiple pneumatic shakers as well as special mechanical shakers are contending for random vibration tests under

-781C. Their acceptance depends upon detailed interpretation of vibration test requirements and is not assured at the present writing. These types of shakers were briefly reviewed in 1977 (5, 6, 7).

TEST CONDITIONS PER APPENDIX B

To rephrase instructions found under Section 4.3 of the *Standard*, the stress types and levels found in Appendix B are only to be used if measured or estimated types and levels are not available. With that understood, let us examine key vibration points of Appendix B.

Section 40 requires that every significant life-cycle event be considered, including transporting, handling, installation, checkout and each tactical mission. Environmental conditions are to be combined.

Section 50 is divided into 6 categories according to equipment usage. Section 50.1 provides combined environmental stresses for fixed ground equipment. Mechanical shakers readily generate this sinusoidal vibration. Random vibration tests should be added for screening against poorly soldered connections and other workmanship flaws, in the writer's opinion.

Section 50.2 provides combined environmental stresses for mobile ground equipment, vehicle mounted. Sinusoidal vibration is to be swept 5-500 Hz. Electromagnetic shakers will most likely be used, although the requirement for one inch stroke at low test frequencies may cause difficulty. Some random vibration could easily be added via the same shaker.

Section 50.3 provides combined stresses for shipboard equipment. 0.02 inch stroke is to be held while sweeping 4-33-4 Hz. Mechanical shakers readily generate this sinusoidal vibration. Again, this writer urges random vibration for screening.

Section 50.4 provides combined environments for jet aircraft equipment, including random vibration. When design flight envelopes and specifically designated flight mission profiles are not available, the *Standard* provides Tables B-II, B-III and B-IV (not shown here) for developing environmental profiles. Lacking specific mission times, 1 hour 40 minutes is to be used for fighter aircraft and 6.5 hours for transport/cargo aircraft. An extra benefit from the random vibration is effective screening.

Section 50.4.3.2.1 requires random vibration in one axis. *MIL-STD-810* is referenced for tolerances and for mounting. The acceleration spectral density of applied random vibration, as measured on the test fixture at the mounting points of the test item, is to be obtained from Figure B-4. Ordinate value W_0 is to be obtained from Table B-V, Figure B-5 (dynamic pressure units should be lb/ft^2) and the general notes which follow. W_1 is 3 decibels less than W_0 .

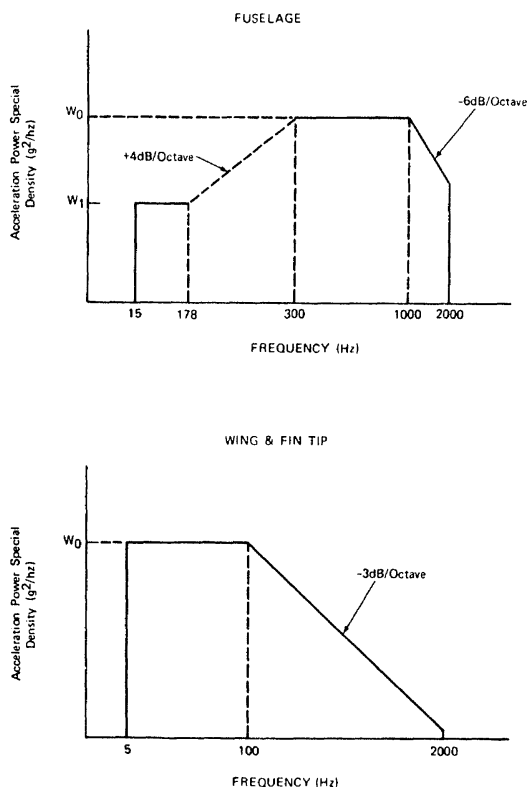


FIGURE B-4

Jet Aircraft Random Vibration Test Envelope

Aerodynamic Induced Vibration

$$W_0 = K(q)^2 \quad q = \text{Dynamic Pressure (when } q > 1200 \text{ psf use 1200) (See 50.4.3.2.2a)}$$

$$W_1 = W_0 - 3 \text{ dB}$$

(FIGURE B-2 for Spectrum Shape)

<u>K</u>	<u>Equipment location</u>
$.67 \times 10^{-8}$	Equipment attached to structure adjacent to external surfaces that are smooth, free from discontinuities.
$.34 \times 10^{-8}$	Cockpit equipment and equipment in compartments and on shelves adjacent to external surfaces that are smooth, free from discontinuities.
3.5×10^{-8}	Equipment attached to structure adjacent to or immediately aft of surfaces having discontinuities (that is, cavities, chins, blade antennas, and so forth)
1.75×10^{-8}	Equipment in compartments adjacent to or immediately aft of surfaces having discontinuities (that is, cavities, chins, speed brakes, and so forth)

SPECIAL CASE CONDITIONS

Fighter Bomber

<u>Condition equipment location</u>	<u>W₀</u>
Take off/attached to or in compartments adjacent to structure directly exposed to engine exhaust Aft of engine exhaust plane (1 minute)	.7
Cruise/(same as above)	.175
Take off/in engine compartment or adjacent to engine forward of engine exhaust plane (1 minute)	.1
Cruise/(same as above)	.025
Take off, landing, maneuvers/wing and fin tips* deceleration (speed brake) (1 minute)	.1
High q (> 1000 psf)/wing & fin tips*	.02
Cruise/wing & fin tips*	.01
Take off/all other locations (1 minute)	.002

Cargo/Transport

<u>Condition/equipment location</u>	<u>W₀</u>
Take off/fuselage mounted	.01
Take off/internal	.005
Take off/wing-Aft of engine exhaust**	.05
All/wing tip and fin tip***	.01

* Use wing and fin tip spectrum - FIGURE B-4

** Excludes Upper Surface Blown (USB) and Externally Blown Flap (EBF)

*** Take off, landing, plus 10 percent of cruise time

TABLE B-V
Jet Aircraft - Random Vibration Test

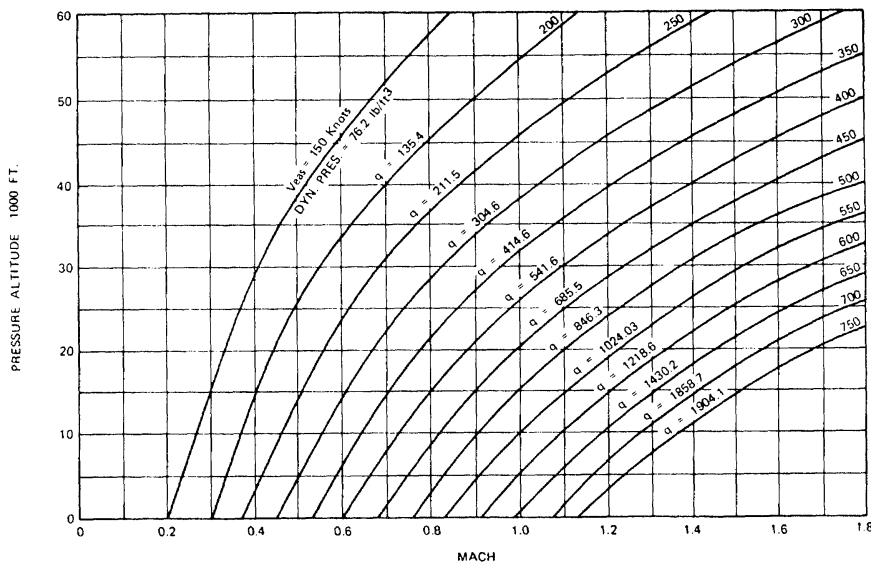


FIGURE B-5
Dynamic Pressure (q) as Function of Mach Number and Altitude

50.4.3.2.2 General notes.

- Determination of mission profile vibration levels. The vibration level for each phase of the profile will be determined from TABLE B- V. A maximum of four W_o 's will be determined by: (1) take off; (2) q_{avg} ; (3) q_{10} ; and (4) q_{avg} . Where q_{max} is the maximum aerodynamic pressure encountered during the mission, usually at 10000 altitude, high speed dash; q_{min} is the aerodynamic pressure associated with the flight phase that will generate a W_o above .001 g^2/Hz , normally a cruise condition. The fourth vibration level shall be determined by combining the vibration levels calculated for each of the other phases (climb, dive, combat, and so forth) having levels above the minimum (see c. below). An average q shall be used for each flight phase, that is, for a phase such as dive, the arithmetical average of the q at the start of the dive plus that at the termination of the dive shall be utilized ($q_{start} + q_{term}$)/2 = q_{avg} . A W_o shall be calculated for each phase and flight phases with W_o 's above the minimum shall be time weighted averaged to determine the fourth vibration level.
- Cargo aircraft. Unless unusual mission profiles are determined, take off and cruise profiles (vibration levels) will be the only required vibration levels.
- Minimum W_o test level. The minimum W_o test level shall be .001 g^2/Hz . If the calculated test level is less than .001 g^2/Hz , vibration test is not required during this portion of mission profile.
- Option. Maximum W_o determined may be used throughout test.
- Gunfire environment. Not considered in this test. Should be considered in environmental qualification test, if applicable (MIL-STD-810).
- Composite vibration profile. Turboprop and jet aircraft usage; when equipments are to be installed in both turboprop and jet aircraft, a composite random spectrum shall be generated (see FIGURE B-6 for example, composite spectrum).
- Wing and fin tip, fuselage equipments. When equipment is to be installed in both locations, a composite vibration profile shall be utilized where appropriate.

An example of the construction of a mission test cycle profile is given under Section 50.4.4 of the *Standard*. Assumptions:

- Equipment Class 2 in accordance with MIL-E-5400
- Equipment installed in air-conditioned compartment
- Equipment is ambient cooled (no supplemental cooling)
- Equipment is attached to structure adjacent to external surfaces that are smooth, free from discontinuities
- Altitudes are shown in Figure B-7 (not shown here). The vibration conditions for each phase (two flights) are shown in Tables B-XIV and B-XV (next page).

Phase A, lasting 30 minutes, represents cold day operations, no vibration. Phase B contains one minute vibration to represent cold-day takeoff and 6 minutes to represent climb to 30,000 feet. Phase C represents 23 minutes Mach 1.0 cruise, two minutes Mach 1.0 dive to 10,000 feet, 5 minutes Mach 1.0 intercept maneuvers, 13 minutes climb to

TABLE B-XIV
Calculations for Vibration Test Levels

Test phase	Altitude (feet)	Mach number	W_0 (g^2/Hz)	Duration (minutes)
A Ground Operation	0	0	0	30
B Take Off	0	0	.002	1
B Climb	1-30 K	.6	.0006*	6
C Cruise	30 K	1.0	.0012	23
C Dive	30-10 K	1.0	.0035**	2
C Intercept	10 K	1.0	.0067	5
C Climb	10-40 K	1.0-.6	.002**	13
C Cruise	40 K	.6	.00006*	35
D Descent	40-0 K		.0004*	15

- * In accordance with 50.4.3.2.2c value below minimum therefore no vibration is required.
 ** Mix vibration levels = $(.0035) (2) + (.002) 13$ determined by time weighting vibration levels for major flight phases.

40,000 feet and 35 minutes Mach 0.6 cruise to base. Phase D represents 15 minutes idle descent to a hot-day landing. Phases E through J represent similar operations starting with a hot and ending with a cold day. Vibration testing is not required when levels are less than $0.001g^2/Hz$. Levels for the "dive" and the "climb" phases have been time averaged. These manipulations simplify conducting tests.

Section 50.5 provides combined environments for turboprop aircraft and for helicopter fuselage-located equipment. Gunfire-induced vibration should be considered when an equipment is destined for attack helicopters; Method 519.2 of MIL-STD-810 should be consulted.

Section 50.5.3 calls for swept-sine vibration, one sweep in 12.5 minutes (10 minutes for Army). The writer is told of plans⁽⁸⁾ to change Figure B-6 (which accordingly is not reproduced here) and some of the text under 50.5.3. Random vibration is not contemplated under 50.5.3. The writer feels this to be a mistake; some random vibration, at least for workmanship screening, should be added.

Section 50.6 provides combined environments for air-launched weapons and assembled external stores. MIL-STD-1670⁽⁹⁾ is referenced for environmental criteria and guidelines. Unfortunately, while -781C was being developed, -1670 was replaced by -1670A⁽¹⁰⁾. The latter is somewhat condensed; it does not give spectra, but rather refers users to MIL-STD-810.

CONCLUSION

Flight environments have changed greatly since World War II. But the vibration portions of long-time reliability-demonstration tests have stuck with pre-War technology. This writer, for one, is delighted that broad-spectrum random vibration (and acoustic) testing is at last replacing the single-frequency tests of MIL-STD-781, -A and -B. An important message may be seen by reading -781C, -810C and -1670: the military services want greater realism in vibration testing (reliability demonstration as well as qualification). They also want equipments screened for workmanship flaws.

TABLE B-XV
Final Vibration Test Conditions for Example

Test Phase	Vibration Level (g^2/Hz)	Duration (minutes)
A, F	0	30
B, G	.002	1
B, G	0	0
C, H	.0012	23
C, H	.0067	5
C, H	.0022*	15
C, H	0	35
D, I	0	15
E	0	--

* Mix vibration level.

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LCS 850:70:991

AN INTEGRATED QUALITY SYSTEM
ANSWERS THE CHALLENGE

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INTRODUCTION

We were asked to set up a comprehensive quality control system for a product that was pushing the state of the art and causing a serious low yield by our subcontractor. The situation facing us was this: an unknown product, an enigmatic and sensitive series of processes, a high-production condition, and a high cost per unit. Since the typical aerospace condition is one of low production rates, the product challenged our customary quality control methods.

This paper recounts how we handled the new product and the unusual conditions. It can provide the basis of an approach to someone confronted with a similar problem. As a context for the rest of this presentation, a brief description of the product and process follows:

The thermal protection system for the Space Shuttle orbiter consists of a high-purity silica-fiber insulation built as a tile and designed to protect the vehicle structure against temperatures of 2300°F during atmospheric reentry. Each Shuttle vehicle will require approximately 34,000 tiles in thousands of different configurations capable of withstanding repeated heating and cooling, plus extreme acoustic environments, for up to 100 flights without significant refurbishment or replacement between flights.

The basic raw material is a 99.7-percent pure amorphous silica fiber. It is cast, dried, and sintered to form lightweight silica blocks, which are then machined to the required dimensions. A coating of borosilicate glass is applied and sintered at temperatures of 2100 to 2200°F to fuse the glass coating. Treated with a waterproofing agent to prevent absorbing extra weight from rain or humidity, the tiles are then bonded to a pad of Nomex felt (used as a strain stress isolator) for installation on the Shuttle orbiter.

PRE-PRODUCTION QUALITY INVOLVEMENT

The need for early involvement in process planning cannot be overemphasized. It is here the quality control professional establishes working relationships with his manufacturing and engineering counterparts. This was especially true when ceramic processing technology was introduced into aerospace. It was realized that the quality control practitioner had a certain expertise in process control. So instead of being driven, as is usually the case, the quality engineer was part of an integrated approach from the beginning.

Process Control Emphasized

The strategy used for this critical and creative phase of the process was to concentrate on control of the process rather than inspection of the product.

The key then was understanding the process, for which a detailed flow chart of the manufacturing processes were prepared. Figure 1 presents a section of this manufacturing/processing flow chart. The chart depicts each operation performed, quality characteristics to be inspected, controls on raw materials, applicable inspection and test instructions, sampling plans, and control charts. This technique enabled the quality/process control engineer to locate the inspection activities to the best advantage while minimizing the impact on the upstream manufacturing activity. In addition, it allowed him to keep his finger on the pulse of a dynamic process and provided him with the flexibility of changing inspection stations and operator verification points as data were gathered during the process. The chart stresses maximum use of operator (Manufacturing Department) verification points while still maintaining a disciplined quality system with maximum flexibility and operator feedback.

The operator verification approach stems from two considerations. First, involving the technician in the inspection of his work raises his consciousness of the product's quality. Not only is he solely accountable for delivery of the product on time, but also he is made aware of his role in the quality of the product when it is delivered to the subsequent manufacturing stations. Second, involving the manufacturing technician in the inspection tasks is more cost effective. Inspection tasks delegated to the operator verification system encompass items that can be verified visually. Tasks that are critical or require special knowledge or unique inspection devices are not delegated to manufacturing.

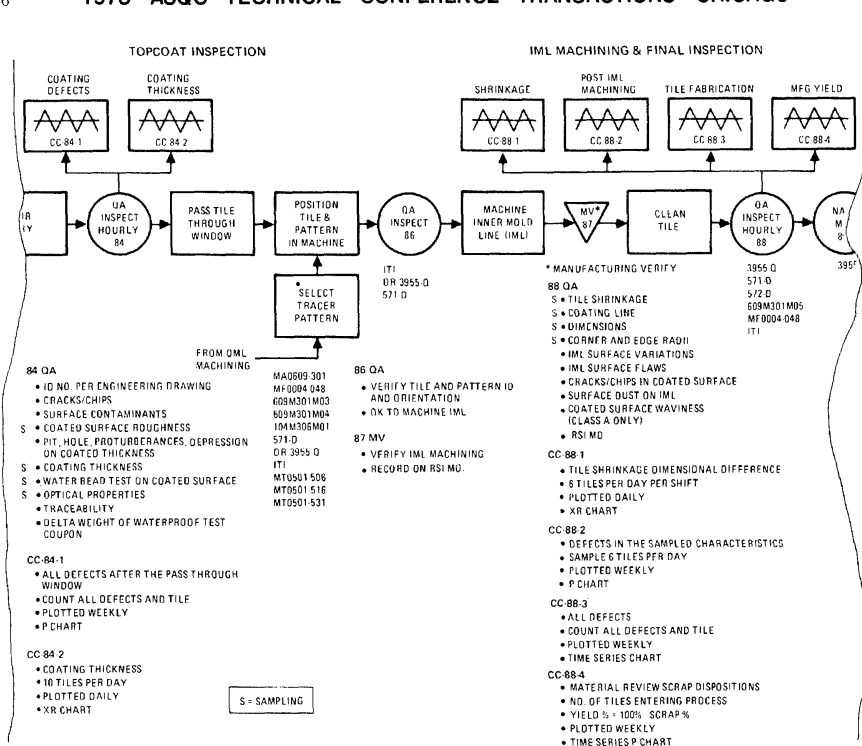


Figure 1. Manufacturing and inspection flow chart.

Thus, what started as a process logic flow to understand the process ultimately grew to a quality planning document, which proved to be invaluable in subsequent planning.

Although the flow chart enables the quality/process control engineer to cover the "big picture" effectively, another means of collecting the details of the quality assurance process is required. Figure 2 provides a method for defining product characteristics: what, when, how, how many, etc. In addition, when incorporated into the manufacturing/processing flow diagram, the inspection definition provides an easy and accurate method for predicting manpower needs.

Traceability

Coupled with the need for critical process control was the need to maintain traceability. Key elements of the process, including subcontractor billet numbers, coating slurries, and waterproofing agent lot numbers, had to be recorded against each tile and tile lots produced. The total number of characteristics that require traceability

FLOW CHART
PALMDALE LMSC
BLOG
HRST LRST CLASS 1 CLASS 2
TILE

ITEM INSPECTED	ATTRIBUTE	CHARACTERISTIC	DISCRETE VARIABLE	INSPECTION DOCUMENT	TYPE OF INSPECTION	INSPECTION INSTRUMENT	INSPECTED BY	CERTIFICATION	BATCH SIZE	# OF ITEMS PRODUCED	PROCESS AVERAGE	TRACEABILITY	INSPECTION FREQ.	DOCUMENT FOR RECORDING INSPECTION	FEEDBACK OF INFORMATION	TIME BETWEEN MFG AND INSPEC
Tile	Coating	Crack	D	ITI 88-1	Visual	Alcohol wipe	QA	Yes	10 tiles	30/day	81	Yes	100%	571-D	P chart	2 days
	Coating	Water Imperviousness	D	ITI 88-2	Visual	Water bead test set	QA	No	10 tiles		41	Yes	AQL 41	571-B	P chart	1 day
	Dimension	Width/length	V	ITI 88-3	Dimensional	Dial indicator	QA	No	30 tiles		51	Yes	AQL 41	573-D	X R chart	2 weeks
Tile	IML Surface	Void	D	ITI 88-4	Visual	Scale	QA	No	30 tiles	30/day	11	Yes	100%	571-D	P chart	1 day

Figure 2. Quality characteristics analysis of tile fabrication, Inspection Station 88.

equaled 32. The typical two-way street of traceability—raw material to installation to raw material—had to be economically maintained. Since the traditional methods of operation relative to procedures and documentation were difficult to sever, existing systems were tailored to the needs dictated by the process. Volume alone would have made traditional systems unworkable.

Pooling the resources and talents of various organizations within the quality/manufacturing management structure made it possible to simplify the manufacturing order (the record that accompanies the part to be fabricated) while traceability through the use of the process control record (Figure 3) was maintained. The process control records (PCR's), serialized by date, contain all information pertinent to the process; e.g., slurry roll time, gun delivery rates, batch numbers, operator numbers, and product serial numbers. The PCR serial number is then cross-referenced on each manufacturing order against each specific operation performed. Thus all data are entered on the PCR, which enables the processing and traceability data to be easily retrieved by either serial number or lot number. Data relative to the process were maintained by the operator at each processing station. A job classically done by inspection was thus delegated to the Manufacturing Department, with minimal surveillance by inspection.

PCR 63 CLASS 1 & CLASS 2 KILN SET-UP		DATE 01 03 78	PAGE 01				
Process Control Record (Log Sheet)							
SET-UP TIME <u>0700</u>		KILN SETTINGS CLASS <u>II</u>					
<div style="border: 1px solid black; width: 100px; height: 100px; margin: 0 auto; transform: rotate(45deg); transform-origin: center; position: relative;"> </div>	DIGITAL SET POINTS				ROLLER RATES - FPH		
	ZONE 1	ZONE 2	ZONE 3	ZONE 4	DRIVE 1 (RED)	DRIVE 2 (BLUE)	DRIVE 3 (GREEN)
	PREV. 2200	2192	2220	2205	300	8	800
NEW	2200	2176	2225	2210	300	8	800
THERMOCOUPLE READINGS							
THERMOCOUPLE NO.	4	5	6	7			
TEMP RDG - °F	2203	2200	2203	2204			
OPTICAL PYROMETER READINGS							
RDG NO.	TIME	TEMP - °F	RDG NO.	TIME	TEMP - °F		
1	11:20	2208	6	12:35	2197		
2	11:35	2212	7				
3	11:50	2211	8				
4	12:05	2216	9				
5	12:20	2212	10				
PYROMETRIC CONES							
TIME ENTERED KILN	TIME EXITED KILN	TIME ELAPSED	CONES ACCEPTED ▼				
11:05	12:40	95	YES				

▼ MANUFACTURING VERIFY
● INSPECTION

Figure 3. Process control log used for traceability.

To summarize, the systematic approach used during the preproduction phase enabled Quality Assurance to move smoothly into the production phase and avoid the confusion of developing a quality system in parallel with initiating a new product or process.

The flow chart facilitated communication among Quality Assurance, Engineering, and Manufacturing and insured satisfaction of common goals. Since the flow chart was developed in the Quality Assurance function and later adopted by the other two functions, Quality Assurance took the lead in planning during the preproduction phase. This in itself can be considered a "first."

PRODUCTION QUALITY INVOLVEMENT

Since the strategy for this process was to stress process control rather than product inspection, timely feedback of information was critical. Feedback mechanisms, in the form of control charts, were designed around each inspection station to provide the operator and management with real time data. Characteristics to be inspected had been carefully set forth on the manufacturing process flow chart and this, coupled with the process control records, provided Quality Assurance with the tools to glean the needed information for control charts and to perform meaningful analyses.

The statistical techniques employed are those of the classical textbooks on quality engineering. Because fabrication of these tiles requires multiple steps and involves numerous variables, a fundamental statistical method employed was analysis of variance (ANOVA). Potential interaction effects usually involve several independent variables and require more sophisticated ANOVA models. However, when the analysis of variance revealed that no interactions existed, the data could be more effectively communicated by control chart techniques.

Both X bar and P charts have proved effective in feeding back the information to the responsible departments. When feasible, the chart is plotted by the manufacturing technician who is performing and verifying the work being monitored. This involvement eliminates the criticisms of some technicians, who call the control chart concept too remote or impractical. It gives the technician immediate information relative to his responsibility in a format easy to interpret.

SUMMARY

Our experience has demonstrated that Quality Assurance not only can become an integral part of a team composed of Manufacturing and Engineering, but also can be the integrating force. We were successful in this role because we were systematic and comprehensive in our approach to the quality matters and because we became involved early in the process. Another factor is that Quality Assurance defined its strategy: we claimed responsibility and accountability for developing information feedback systems so that those responsible for action had valid and timely data. The confirmation of this careful planning is that we have experienced a yield rate of over 90 percent and have met our early budget commitments.

We have also confirmed that the classical Quality Control concepts work. Control charts, Pareto analysis, analysis of variances and the other traditional textbook tools of the quality engineer are indeed his tools; perhaps he alone of the team members from Manufacturing and Engineering has the expertise in the collection, processing, and interpretation of the data. In 1931, W. A. Shewhart wrote the first textbook devoted to quality control. He entitled it *Economic Control of Quality of Manufacturing Product* and his theme was that quality control does contribute meaningfully to the economics of manufacturing processes. It has been our experience that Shewhart is still timely.

LCS 310:70:439

TEST: TOLERANCES & MEASURING -
BOTH VITALLY WEAK IN Q.C.

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In the control of quality, in its assurance, and in auditing quality we MEASURE against pertinent STANDARDS. Even if the quality characteristic happens to be a cosmetic, visual one, we should still have a reference, a standard for deciding we are IN or OUT of specification. Judgment can vary more if the standard is a mental, opinion (of workmanship appearance) one; so most companies keep a physical "limit sample" to serve as a borderline acceptable reference for each such characteristic of some importance.

Statistical quality control developments in manufacturing process control, and in acceptance sampling have been substantial over the years. Surprisingly, similar efforts were not expended in statistically evaluating the quality of the "numbers" for the two basic parameters capitalized in our opening sentence: the definition of quality and the validity of the measurements of the product. Apparently, it has been too easy for managers to assume that tolerances which survive with time and extensive product use must be close to correct; and to assume that periodic reinspection of gages and instruments against reference masters under metrology room conditions represents all, or about the best, a company can do.

A non-statistically, usually arbitrarily, selected tolerance almost always adds a non-productive cost. And we have found that many measuring devices change in their calibration when they leave the metrology room and are used under operational environments. That is not surprising. What is unexpected is that usually gages that are the same design do not change in their settings the same amount. Let's define such differences as gage-to-gage bias.

I. MEASURING

Ironically, those differences often DISAPPEAR when the gage's original settings are rechecked back under metrology conditions. Accordingly, management of this problem needs information about the mean and the dispersion (precision) of the measuring instruments under operational environments, instead of under calibration environments. One of these environments is the true, but unknown, product to "similar" product variation, ΔP , which sometimes disturbs the uniformity of the bias.

For a remarkably effective plotting strategy, enter the results from two similar gages for at least 30 different units of product, on a two-coordinate graph with equal scales, one for gage #1, the other for gage #2. Each plotted point represents the pair of readings on a single unit. By eye, encompass the points with an ellipse, touching the boundary points, or excluding the one "most extreme" point. That ellipse becomes a rough, but not-too-bad estimate of a 95 percent probability contour (excluding 5 percent of 30 points, which would be 1-1/2 points).

Draw a straight line from the origin at a 45 degree angle to a coordinate axis. It represents the line on which all equal readings from the two gages will lie. If the major axis of the ellipse lies on that 45 degree line, the two gages agree, on the average. A rather common surprise is the discovery of a displacement from, and sometimes an angular relationship of the major axis to the 45 degree line. That "bias" between the two gages reveals the nature of the systematic error

introduced on the job, unexpected by the fact that both were released by metrology control as being alike.

In addition to possibly having a displaced mean result, a gage has a certain degree of lack of repeatability, called its imprecision. The 30 perpendicular distances from the points to the 45 degree line represent a sample of 30 estimates of just the measuring error from both gages. No product variation contributes to those perpendicular distances, because product variation (ΔP) only causes the points to move parallel to the 45 degree line, toward or away from the origin.

Thus the small width dimension of the ellipse, which is perpendicular to the 45 degree line, can be used as an estimate of ΔM , measuring error. This estimate improves as the true ΔM 's for each of the two gages approach being equal to each other.

At 90 degrees to this dimension, mark off the large dimension of the ellipse as a parallel length, along the 45 degree line. With that length being the hypotenuse of a 45 degree right triangle, 0.707 times it will be the length of one of the shorter sides, equal to the chance combination of ΔP and ΔM variation. The variances of those two independent estimates add statistically. Thus the square of that short side length equals $\Delta P^2 + \Delta M^2$. The solution from that equation for ΔP provides a statistical estimate of the true ΔP from the sample of 30 points. Here we are estimating the true product variation, with all the ΔM gage error removed, regardless of the imprecision of the gage.

The ability of this plotting strategy to furnish independent estimates of gage bias, gage precision, and true product variation has led to a growing number of useful adaptive applications:

- qualifying the discriminatory precision of the measuring method for the measuring task: e.g. when the ratio of $\Delta M/\Delta P$ is 1/6 or less, the method will give single readings with an error of 1/36 (+1.4%) or better.

- comparing the relative abilities of two or more technicians or inspectors to perform their evaluation tasks alike.

- vendor versus buyer ability to agree on the evaluation of a quality characteristic.

- laboratory to laboratory differences.

- comparing two or more different measuring equipments, or methods.

- even two or more different formulae have been compared statistically for calculating a performance parameter from a number of input measurements.

The reader is expected to extend this list.

II. STANDARDS

A quite different plotting strategy has statistically evaluated the quantitative tolerances for raw material, manufacturing processes, parts, subassemblies, etc., intended to result in certain acceptable output, or final product, quality characteristics. A statistician would name the input tolerance as defining the independent variable; the output requirement as the dependent variable.

To evaluate the validity of the limits for any independent characteristic, measure a series of 30 inputs on typical (random) parts, and tag each with its value, later to be plotted on the x-axis of a graph. Whoever originally specified a tolerance for that x felt it might, or would, have an influence on at least one output, causing that dependent variable y to vary. The 30 tags will permit you to evaluate the validity of that influence, IF IT EXISTS AT ALL! When those parts are assembled,

combined with others to make a subassembly, or a finished product, the corresponding 30 y output measurements are entered on each tag moved from the part to the assembly containing it.

The graph displays the 30 (x, y) points. Again, by eye, encompass the points with a 95 percent contour ellipse, or a circle if that be the case, and interpret the outcome.

When the axes of the ellipse are parallel to the x, y coordinate axes, or when you have a circle, a change in x produces no change, on the average, in y. The selection of the interval size for plotting the x-axis and for the y-axis have a bearing upon this observation. Use this "rule of thumb": Be sure that the scale interval you select for the 30 points shows 7 or more intervals on each axis. Too coarse a scale will desensitize the information sought.

But when the axes of the ellipse are tilted, an average influence of x upon y is indicated. In that case draw, again by eye, a major axis of the ellipse, with 15 of the points above and below it, called the regression line or curve in the accompanying illustration. Also draw a pair of parallel, 95 percent boundary lines, equidistant from the regression line.

Your customer, if he is like most customers, has clearly established his requirement for y in terms of a tolerance. If he has specified both a maximum and a minimum, extend a horizontal line from each to the upper and to the lower boundary lines, respectively. From those intersection points, as shown in the illustration, drop lines perpendicular to the x-axis. You can see that if production, in the future, complies with that new, indicated realistic manufacturing tolerance for x, virtually all the future points might be expected to lie within a parallelogram, and all between the customer's desired limits.

A most cost-effective characteristic (of this procedure for maintaining traceability of each of the 30 x's to the y of the assembly or system they enter) is that the identical 30 assemblies can show a possible relationship to 30 x_1 's, 30 x_2 's, x_3 's, etc. Just use more tags.

With n different input tolerances, expect this evaluation with the single set of 30 assemblies to follow the Pareto principle: One, or very few of the x's may be found to be vital; the great majority will have trivial or no influence upon y.

To distinguish the vital from the trivial, do not compare their plotted slopes. Each x has its own scale, different from the others. Scale selection influences the apparent slopes.

Instead compare the Δy , for a fixed value of x, between the boundary lines. All the y axes on the different x graphs should be plotted with the same scale for the one set of 30 output measurements. To identify the x that has the greatest influence upon the required y output, notice that its chart will exhibit the narrowest Δy for a fixed value of x (between the two arrow heads in the illustration).

Ironically this evaluation procedure, for a number of x's suspected to have an influence upon an important customer y, often reveals that all the x's have virtually no significant influence. The ellipse axes parallel the x,y axes. The vital x remains unsuspected then, or even not specified. But please remember: No y variation occurs without some cause. You become a real manager of quality when you persist in your search for the most vital x. You improve your company's ratio of quality to cost, which can be called product "value" to the customer, when you open up unnecessarily tight tolerances, and graphically estimate, then confirm with new x,y data, the realistic tolerances for the important x's.

The remaining step relates to important visual, rather than quantitative standards. An evaluation of the ability of important customers to pass

a rank order discrimination test serves well here. A minimum sample of six items can work with 95 percent confidence. Three parts are representative of the present limit sample, described in our opening paragraph. The other three are examples of a new, less rigid limit sample that would save a computed number of production dollars - successfully with no quality penalty if customers cannot tell the two standards apart.

The test for typical, important customers: "Please rank these six items as 1 to 6 from best to worst for this visual characteristic we are pointing to." If they succeed in placing the three tight ones in the top ranks, they can see the difference. But if they fail to separate the tight three from the looser three, our present limit sample is failing to achieve anything with its higher cost.

Since there are 20 different ranked order arrangements possible of 3 tight and 3 loose items, only 5 percent of the time will the tight ones rise to the top ranks if each evaluator is only guessing. If he really cannot discriminate, 95 percent of the time we shall be protected against keeping the expensive, unnecessary tight standard. If he clearly can discriminate, then 100 percent of the time we shall maintain the tighter limit sample.

This paper has suggested that you, too, as many companies have now done, extend the rather simple statistical strategies of quality control to measurement evaluation with 45 degree comparison graphs and to establishing realistic standards for important characteristics by objective tests:

- does a current range of x influence y as intended?

- can the customer tell the difference between one qualitative standard for y and another less demanding?

You owe it to your professional wellbeing to serve your company in controlling and assuring quality objectively.

LCS 710:60:439

DETERMINING REALISTIC TOLERANCES
FROM SCATTER PLOT

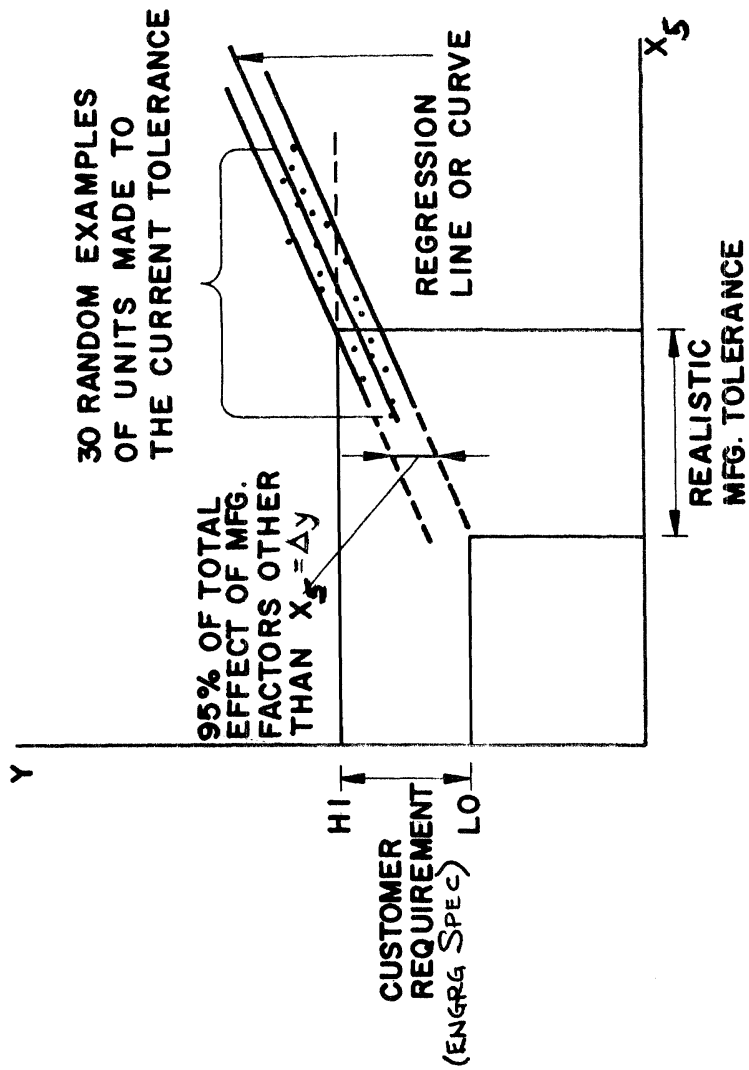


FIGURE 1

ESTIMATING AUTOMOTIVE RELIABILITY

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INTRODUCTION

Reliability from a theoretical standpoint is a reasonably well understood discipline that has experienced considerable research effort over the last twenty years. Reliability is usually defined as the probability that a system will perform its intended function adequately for a specified interval of time when operating under stated environmental conditions. Any system has an inherent reliability level due to the parameters of the design. That is, the reliability level is established at the design phase, and subsequent testing and production will not raise the reliability without a basic design change.

Implementing a reliability program in a consumer industry always presents some unique problems. First of all, reliability is a probabilistic concept, and its measurement must be approached from this standpoint. However, probabilistic concepts and statistical estimation are, at best, poorly understood by many in the design activity. Thus, there is a tendency to use such terms as percent failures or failures per hundred based on simple calculations to represent reliability, and these terms are frequently volume dependent.

Also, even if one addresses the probabilistic nature of reliability from a rational standpoint, other problems will be encountered. With commercial products, the environmental conditions must usually be taken as those encountered in use. This is indeed a problem since commercial products (and particularly vehicles) will experience wide variability in use. Since just a few failures can promote a recall campaign of extremely costly consequences, the tendency is to over design to provide a wide margin of safety particularly for critical items.

Product testing is usually not conducive to reliability estimation for two reasons:

- (1) The testing is not extensive enough particularly for highly reliable products, and
- (2) Any design deficiencies that show up during testing are corrected. So, the basic design is continually improved throughout testing and only stabilizes when it is released to production.

Eventually, the products reach the consumer market, experience field use, and some occasionally do fail. Typically products have a warranty period, and failures during this warranty period are reported back to the manufacturer by way of an information system. In order to measure, compare, and improve product reliability an estimation procedure is needed based on the particulars of this situation. That is, estimation is frequently situation oriented in that standard techniques must be tailored somewhat to the situation at hand.

This paper focuses on a particular product and industry - the automobile. This product has a significant impact on the consumer market and considerable effort is expended in design improvements. Estimated reliability is used as one input to decisions for re-design and engineering changes. The information source most frequently used for predicting vehicle reliability is quite similar from manufacturer to manufacturer and is essentially a warranty (or failure) reporting system. The next section will briefly discuss some reliability prediction methods in common use based on warranty data.

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BRIEF REVIEW OF COMMONLY USED METHODS

Vehicle reliability determination is not a new problem and one may rightfully ask, "What methods are presently being employed?" Review of presently used methods also serves to provide familiarity with the particulars of the problem situation. The methods reviewed herein have been developed by various individuals working in different automobile companies over a number of years. It is extremely difficult to trace original authorship of these methods. Thus, with apologies, authorship is not acknowledged. Also, it must be recognized that this review may not be complete, since it is difficult to extract company information on this subject. The review is essentially based on our experience with engineers from various automobile companies.

One simple and frequently used method is to plot the failure odometer readings on Weibull paper. Another method is to sum failure odometer readings of reported failures and divide by the cumulative number of failures. The problem with these methods is that the unfailed or suspended mileage is ignored, and the calculations are not really indicative of the true reliability. Some also use failures per 100 vehicles sold (or produced) and term this R/100. This is roughly equivalent to the "failures as a percent of sales" method to be explained in more detail in the next section.

Failures as a Percent of Sales (or Production)

This is a simple and supposedly easily understood method used for tracking warranty failures and hence warranty costs. For a particular vehicle line the ratio of total failures, to date, to total sales (or production) is calculated as a percentage. This percentage is plotted over time to indicate trends and to predict final warranty costs. So, for example, if sales, to date, was 300,000 vehicles with 280 reported failures, the resulting percentage would obviously be 0.09.

Recognize that variability in the volume of monthly sales affects this ratio, because the vehicles sold in the early months have a longer time to accumulate failures than those sold in recent months. However, the thought may be that sales are relatively stable over time, and this ratio allows a convenient tracking method for comparison, by month, to indicate improvements and also to predict final warranty expenses. But sales do vary from month to month, and also, this method has one other subtle fallacy that will now be explained by way of a simple example.

Basically the problem results from, first of all, the change in the size of the warranty population due to production, and secondly, the losses from the warranty population due to the limited length of the warranty period. Let us take a very simple and somewhat hypothetical example to illustrate this phenomenon. It will be assumed that exactly 100 vehicles per month are produced and all sold precisely on the first day of the month. It will also be assumed that each vehicle is driven exactly the same number of miles per month, and the failure rate is constant such that 100 vehicles will generate one failure per month, on the average. The period of production will be taken as four months and an eight month warranty period will be used. Although this is very hypothetical it serves for illustration. Based on this situation Table I can be generated.

Table I Calculation of Failures as a Percentage of Sales

Month of Model Year	Production in No. of Vehicles	Cume Vehicles	No. Vehicles Under Warranty	No. Failures Reported	Cume Reported Failures	Failure as a Percentage***
1	100	100	100	1	1	1.0%
2	100	200	200	2	3	1.5
3	100	300	300	3	6	2.0
4*	100	400	400	4	10	2.5
5	0	400	400	4	14	3.5
6	0	400	400	4	18	4.5
7	0	400	400	4	22	5.5
8**	0	400	400	4	26	6.5
9	0	400	300	3	29	7.25
10	0	400	200	2	31	7.75
11	0	400	100	1	32	8.0
12	0	400	0	0		

* Last month of production

** Last month of warranty for vehicles produced during first month of model year.

*** Failures divided by cume vehicles sold or produced.

The thing to note in Table I is that the percentage used for tracking and prediction purposes is calculated as cumulative failures to cumulative production (or sales) but the number of vehicles producing the failures in the warranty reporting system are those under warranty, and this population changes. A more accurate method would be to calculate cumulative failures to number of vehicles under warranty; however, in "real life" this is ignored because the size of this population is not readily known.

Charting the above calculated percentage over time can lead to some erroneous conclusions when plotted by month, on simple graph paper. For long production periods of ten months and 12 month warranty periods one can be led to first conclude an increase in warranty claims, and then eventually a tapering off when in fact no change has taken place. In the "real life" situation the month to month sales variability and randomness of failures help to mask this underlying trend and make the results seem plausible.

The Average Exposure Method

The average exposure method was apparently posed to alleviate some of the problems with the previous method. Basically this method calculates percentage of failures as before, but plots this percentage using something termed the average number of months of exposure. The method can be illustrated with the previous data of Table I. We will now assume, however, that sales (or production) are uniform throughout the month. As one proceeds through the model year the average age, "timewise," of the warranty population will vary; thus, a quantity termed average exposure is calculated as shown in Table II. The failure percentage is then plotted against this average exposure time.

The motivation behind this method is to obtain a comparable and predictable straight line relationship. However, this is not necessarily accomplished, and again this method is not amenable to direct reliability estimation.

Table II Average Exposure Calculation

Month of Model Year	Exposure Time for Youngest	Exposure Time for Oldest **	Average Exposure (Months)	Percentage Failures***
1	0	1	1/2	1.0%
2	0	2	1	1.5
3	0	3	1 1/2	2.0
4*	0	4	2	2.5
5	1	5	3	3.5
6	2	6	4	4.5
7	3	7	5	5.5
8	4	8	6	6.5
9	5	8	6 1/2	7.25
10	6	8	7	7.75
11	7	8	7 1/2	8.0
12	8		8	

* Last month of production

** Which could potentially appear in warranty report

*** From Table I

Total Mileage per Interval Method

Another procedure in use is aimed at estimating the failure rate. Again the basic information source for this procedure is the monthly warranty report, or failure reporting data as available from Peterson, Howell & Heather (a leasing firm in Baltimore, Md.). The approach is to estimate the failure rate by mileage interval for a vehicle line.

A monthly mileage distribution is developed from warranty reports. This is done by dividing the recorded odometer reading as reported at the time of failure by the number of months since sale of the vehicle. Obviously a monthly mileage ogive can be developed by sampling several hundred cases from warranty reports. Thus, for example, if 15% of the "population" of vehicles accumulated more than 1,000 miles per month, one could use this to compute mileage for the (0-1,000) mile interval by using monthly sales as indicative of age.

In order to illustrate, let us assume that we have the end of December warranty report, and we want to calculate failure rates. Vehicle production by month is readily attainable. Let us say it is as follows:

<u>Month</u>	<u>Vehicle Production</u>
September	20,000
October	16,000

and so forth, for the remaining months. The amount of mileage attributed to each interval by each month's production will be determined by considering the average number of months in use. In order to do this, consider Table III below. Here the first 1/2 month is due to the lag in sales while the last 1/2-month is due to the lag in the reporting of failures through December (using this reasoning it would probably be more correct to use zero months usage for cars produced in December; however, this is not what is done).

Table III Average Number of Months of Use

<u>Month of Production</u>	<u>Months of Use</u>			<u>Dec.</u>	<u>Total Months Use</u>
	<u>Sept.</u>	<u>Oct.</u>	<u>Nov.</u>		
Sept.	1/2	1	1	1/2	4
Oct.		1/2	1	1/2	2
Nov.			1/2	1/2	1
Dec.				1/2	1/2

Of the 20,000 vehicles produced in September the vehicles with 2,000 miles or more on them, would be the ones that averaged over 500 miles per month. This is obtained by noting that September produced vehicles have four months usage. Using the mileage ogive (not included) one might find that there is, say, 97% of such vehicles in the "population." Thus, the mileage contributed to the (0-2,000) mile interval by September built vehicles would be calculated as

$$20,000 \times 97\% = 19,400 \text{ vehicles}$$

$$19,400 \text{ vehicles} \times 2,000 \text{ mi/vehicle} = 38.8 \times 10^6 \text{ mi}$$

For each month of production, the number of miles contributed to the (0-2,000) mile interval is calculated. So, for each mileage interval the total number of miles and total failures in the interval are used to calculate a failure rate.

This method is definitely an improvement over the previous percentage methods; however, there are a few problems. First of all, the basis for the mileage ogive was not the total vehicle population (or a random sample from it), but instead was the population of failed vehicles appearing on the warranty report. The reason for this is obviously due to the ease with which these mileages can be obtained. But this warranty population may be different "mileage wise" than the population as a whole. For example, appearance on the warranty report would be influenced by high mileage drivers. Thus, the basis for mileage calculation is very likely bias.

If this method was to be employed, work would still have to be done to obtain an ultimate reliability function. Obviously, this method has potential for reliability estimation.

A warranty reporting system provides data on all reported failures. It is usually expected that any reliability analysis be done from this same information source. However, any failure reporting system that attempts to report all failures is usually lacking in the quality (or accuracy) of information. For reliability analysis a better strategy is to closely monitor a small subset of the population such that highly accurate data is obtained. In order to accomplish this, a network of select dealers have been identified for the specific purpose of product reliability analysis. The vehicles sold by these dealers are tracked, by failure reporting at the dealer, for a period of three years. The dealers were selected partially on the basis of high return rate of customers [2]*. Thus, although the remainder of this report speaks of total sales, in actual application a subset of the total population is utilized, and total dealer sales for this subset is appropriate.

In a typical manufacturing situation sales are going on continuously, and as units are sold they see a variation of use that depends on customer driving habits. Thus, one must consider this dynamic sales and use environment in order to estimate the mileage on all vehicles in the field. The failure of a vehicle is related to accumulated mileage; however, mileage is only known for failed vehicles. The age of vehicles "time wise" is known, and this is indirectly related to miles of usage.

*List of references at end of article.

Other compounding factors in this situation are the extremely low failure rates, and the lag in time from sales, to mileage accumulation, to failure reporting. For example, one percent failures on a subsystem during warranty would be considered a near panic situation. This indirectly implies a failure rate of $\lambda = 0.8 \times 10^{-8}/\text{mi}$ (assuming an exponential distribution). For a particular vehicle line the total model year production might be 600,000 vehicles. However, this production occurs over a 10 month period. Thus, at the end of the second month of production there may be about 10,000 vehicles actually in the customers hands. If we assume that all vehicles had experienced exactly 1,000 miles of use (probably an over estimate) then we would not expect to see even one failure although the failure rate is at a level we would like to detect.

At this point the scope of the problem should be recognized. The next section considers two further approaches. These approaches are based on two distribution models that are widely used in this industry.

PREDICTION MODEL DEVELOPMENT

In order to estimate vehicle reliability, one approach is to select a failure distribution model. The exponential distribution is widely accepted and is usually appropriate for system level failures where a constant failure rate may apply. However, mechanical component failures are usually due to fatigue, corrosion, etc., and for these failures the Weibull distribution is a more appropriate and widely acceptable model. If the failure distribution is assumed to be exponential, the mean miles between failure (MMBF) parameter can be estimated by determining the total accumulated mileage of the entire vehicle fleet and the the number of failures. If the failure distribution is Weibull, the parameters might be estimated by some variation of the method of least squares by estimating the number of vehicles with mileages that are in between the given failure mileages. A prediction method will now be discussed for each of the failure distributions.

The model development will be confined to one vehicle line. It is assumed that the manufacturer knows the date the vehicles are sold and the mileage and date of a failure. This represents the usual information available for reliability estimation. Only one type or class of failure is considered, and it is assumed that every failure is returned to a dealer (i.e. reported). This assumption would generally be true where a warranty program is in effect and for major component repair specifically for the subset of dealers used in this study.

As in any model development situation, several assumptions were made:

- 1) The incidence of multiple failure on the same vehicle for the same component is assumed negligible during the period of time under consideration.

Thus, all mileages to failure are assumed to be to first failure

This assumption, unfortunately, is necessary due to the reporting systems in common use. Normally, it is extremely difficult for an engineer to obtain information on incidences of multiple failure because of the information-handling capabilities of the reporting system. This assumption has different implications depending on the specific subsystem under consideration.

- 2) The distribution for vehicle miles per month is assumed to be normal.
- 3) The mean of the distribution for vehicle miles per month is dependent upon the month of the year (seasonal effect).
- 4) The standard deviation of the distribution for vehicle miles per month is the same for all months.
- 5) The number of vehicles leaving the population due to accidents, etc. is assumed negligible.
- 6) Vehicles are sold uniformly throughout the month; therefore, in determining mileage in the first month of usage, the vehicles are assumed sold on the fifteenth day of the month.

Exponential Failure Model

For the exponential failure distribution the MMBF can be estimated by[1],

$$\text{MMBF}^* = T/r$$

where T=total accumulated mileage for the entire vehicle fleet and r=total number of failures. The total accumulated mileage would be the summation of the mileages individual vehicles had accumulated from the date of sale up to the date at which the MMBF is estimated. This accumulated mileage is not known, as in the usual case, and hence, must be estimated.

The approach used to estimate the accumulated mileage (T), as needed in order to estimate the MMBF for the exponential distribution, will now be considered. First, two random variables will be defined. Let

y_k = total accumulated mileage of the fleet at the end of the k^{th} month

and

x_j = mileage of an individual vehicle in the j^{th} month

The accumulated mileage of an individual vehicle would be the summation of the mileages driven in each month from the month the vehicle was sold up to the end of the k^{th} month. Since the vehicle was assumed sold in the middle of the month, the mileage in the first month of usage is taken as one-half of the mileage for the month.

The accumulated mileage for all of the vehicles sold in the j^{th} month is obtained by multiplying the number of vehicles sold (S_j) by the mileage random variable for the j^{th} month (x_j). The total mileage is the addition of accumulated mileage for vehicles sold in each month as follows:

$$T = y_k = S_1 \left(\frac{x_1}{2} + x_2 + x_3 + \dots + x_k \right) + S_2 \left(\frac{x_2}{2} + x_3 + x_4 + \dots + x_k \right) + \dots \\ \dots + S_{k-1} \left(\frac{x_{k-1}}{2} + x_k \right) + S_k \left(\frac{x_k}{2} \right)$$

or,

$$y_k = \frac{1}{2} \sum_{j=1}^k S_j x_j + \sum_{i=1}^{k-1} \left[S_i \left(\sum_{j=i+1}^k x_j \right) \right]$$

The above equation holds while the vehicle model is still being sold. When the vehicle is out of model year, the size of the vehicle fleet is fixed. The equation has to be modified slightly as follows:

$$y_k = \frac{1}{2} \sum_{j=1}^m S_j x_j + \sum_{i=1}^{m-1} S_i \left(\sum_{j=i+1}^k x_j \right) + \left(\sum_{i=1}^m S_i \right) \left(\sum_{j=m+1}^k x_j \right)$$

for $k \geq m$, where m = last month of sales.

Since the mileage on a vehicle is assumed to be a random variable, the total accumulated mileage (y_k) is a random variable. The estimator for the MMBF is taken as

$$\text{MMBF}^* = \mu_t / r$$

where μ_t is the mean for y_k . To determine μ_t consider the following.

Under our assumption, we have $E(x_j) = \mu_j$ for the j^{th} month, and the variance is σ^2 for any month. Then for $k \geq m$, the average accumulate mileage is

$$\mu_t = \frac{1}{2} \sum_{j=1}^k S_j \mu_j + \sum_{i=1}^{k-1} \left[S_i \left(\sum_{j=i+1}^k \mu_j \right) \right]$$

and the variance is

$$\sigma_t^2 = \frac{1}{4} \sum_{j=1}^k S_j^2 \sigma^2 + \sum_{i=1}^{k-1} \left[S_i^2 (k-i) \sigma^2 \right]$$

For $k \geq m$, the mean and variance would be

$$\mu_t = \frac{1}{2} \sum_{j=1}^m S_j \mu_j + \sum_{i=1}^{m-1} \left[S_i \left(\sum_{j=i+1}^m \mu_j \right) \right] + \left(\sum_{i=1}^m S_i \right) \left(\sum_{j=m+1}^k \mu_j \right)$$

and

$$\sigma^2 = \frac{1}{4} \sum_{j=1}^m S_j^2 \sigma^2 + \sum_{i=1}^{m-1} \left[S_i^2 (m-i) \sigma^2 \right] + (k-m) \sigma^2 \left(\sum_{j=1}^m S_j^2 \right)$$

An approach for calculating a confidence interval for the MMBF will now be proposed. Epstein [1] has shown that where failures are accumulated over an interval of mileage the confidence interval is

$$(2T)/\chi^2_{\alpha/2, 2r+2} \leq \text{MMBF} \leq (2T)/\chi^2_{1-\alpha/2, 2r}$$

In our situation since, in many instances, r will be large, the Chi-square values can be approximated, and the confidence interval can be written as

$$(4T)/(Z_{\alpha/2} + \sqrt{4r+3})^2 \leq \text{MMBF} \leq (4T)/(\sqrt{4r+3} - Z_{\alpha/2})^2$$

where $Z_{\alpha/2}$ is the $100(1-\alpha/2)$ percentile for the standard normal distribution.

The confidence interval would be correct if T was exactly known; however, in our situation T is not precisely known but is assumed to be a random variable, and this introduces a further source of variability. Consider the following approach. One can obtain a $(1-\beta)$ probability interval given by T_{upper} and T_{lower} that contains the random variable $T = y_k$, with a $(1-\beta)$ probability, since T is a sum of normally distributed random variables. So, the confidence limits on the MMBF are taken as

$$(4T_{\text{lower}})/(Z_{\alpha/2} + \sqrt{4r+3})^2 \leq \text{MMBF} \leq (4T_{\text{upper}})/(\sqrt{4r+3} - Z_{\alpha/2})^2$$

This is considered to be a $(1-\alpha)(1-\beta)$ confidence interval for the MMBF.

The above approach estimates a subsystem MMBF with a related measure of precision as expressed by the confidence interval. The approach requires knowledge of driver habits. A good study of driver habits might allow one to take a stratified sampling approach in order to decrease the variability introduced by driver mileage.

The Weibull Distribution

The Weibull failure model has a cumulative distribution given by

$$F(t; \theta, \beta) = 1 - \exp[-(t/\theta)^\beta], \quad t \geq 0$$

where β is the shape parameter or the Weibull slope, θ is the scale parameter or the characteristic life, and the minimum life is zero. Taking the natural logarithm twice and rearranging the equation into the standard form for the dependent and independent variables gives

$$\ln(t) = \frac{1}{\beta} \ln\left(\ln \frac{1}{1-F(t)}\right) + \ln(\theta)$$

which is clearly of the form $y = (1/\beta)x + A$, and will plot as a straight line on rectangular (x, y) graph paper. Although the following explanation is given as if it was based on plotting on Weibull paper, the thought is to use a least squares approach in a computerized procedure.

Failure mileages establish the abscissa values for plotting on Weibull paper. The corresponding values of the cumulative distribution function $F(t)$ are needed to establish the ordinate values, or one must know the fraction of the population failing prior to each observed sample value (i.e., failure). Several approaches are available for estimating $F(t)$ [5]. However, it should be recognized that for our particular application the sample size (n) will be large, since production is high volume. Thus, in our particular case, we feel justified in simply using j/n where j is the ordering of the failure time.

In the case of warranty data, many vehicles have not failed, and these must be treated as suspended items. The suspended items can be accounted for by giving the failure times an average order number [3,4]. That is, if the data contains only failures, the items (failure times) are ordered and numbered (1,2, . . . ,n) from the smallest mileage to the largest mileage. With suspended items an average order number is assigned to the failure times considering all possible orders if the suspensions had continued to failure. In order to do this a new increment is determined [4]. This is reduced to an easy calculation procedure by the use of a counting increment (N.I.) which is

$$\text{N.I.} = \frac{(n+1) - (\text{Previous Mean Order Number})}{1 + (\text{Number of items beyond present suspended set})}$$

This increment is then added to the previous mean order number for each vehicle failure until another suspension is reached.

The above method is applicable if one knows the number of suspended vehicles and their mileages. If vehicle warranty data is used, the mileages for the suspended

vehicles are not known, and must be estimated. A procedure of estimation for application of the Weibull distribution will now be explained.

The proposed approach is to estimate the number of vehicles in the population that are suspended between the reported failure mileages. The first step is to estimate the mileage per vehicle based on the present varying age of the population. Let z_k = the random variable for miles per vehicle at the end of the k^{th} month. The miles per vehicle is estimated as the total mileage of the entire customer fleet divided by the total number of vehicles sold through the k^{th} month, or

$$z_k = y_k / \sum_{j=1}^k S_j$$

Let

$$f_{ik} = S_i / \sum_{j=1}^k S_j$$

where f_{ik} = the fraction of population sold in i^{th} month taken at the end of the k^{th} month. Therefore, for $k < m$

$$z_k = \frac{1}{2} \sum_{j=1}^k f_{jk} x_j + \sum_{i=1}^{k-1} [f_{ik} (\sum_{j=i+1}^k x_j)]$$

Similarly, for $k \geq m$, and recognizing that $f_{ik} = f_i$ are now constants, we have

$$z_k = \frac{1}{2} \sum_{j=1}^m f_j x_j + \sum_{i=1}^{m-1} [f_i (\sum_{j=i+1}^m x_j)] + \sum_{j=m+1}^k x_j$$

The mean and standard deviation for the mileage per vehicle random variable would be as follows: For $k < m$,

$$\mu_z = \frac{1}{2} \sum_{j=1}^k f_{jk} \mu_j + \sum_{i=1}^{k-1} [f_{ik} (\sum_{j=i+1}^k \mu_j)]$$

and

$$\sigma_z^2 = \frac{1}{4} \sum_{j=1}^k f_{jk}^2 \sigma_j^2 + \sum_{i=1}^{k-1} [f_{ik}^2 (k-i) \sigma^2]$$

For $k \geq m$,

$$\mu_z = \frac{1}{2} \sum_{j=1}^m f_j \mu_j + \sum_{i=1}^{m-1} [f_i (\sum_{j=i+1}^m \mu_j)] + \sum_{j=m+1}^k \mu_j$$

and

$$\sigma_z^2 = \frac{1}{4} \sum_{j=1}^m f_j^2 \sigma_j^2 + \sum_{i=1}^{m-1} [f_i^2 (m-i) \sigma^2] + (k-m) \sigma^2$$

The distribution of the mileage per vehicle, based on our assumption, would be normal with mean μ_z and standard deviation σ_z . The mileage to failure of the j^{th} vehicle is defined as t_j , as reported. The fraction of the population below a particular reported failure mileage would be estimated as

$$P(z > t_j) = \Phi\left[-\frac{t_j - \mu_z}{\sigma_z}\right]$$

where $\Phi(\cdot)$ is the cumulative standard normal. The fraction of the population between two adjacent failure mileages (t_{j-1} and t_j) is

$$P_j = \Phi\left[-\frac{t_j - \mu_z}{\sigma_z}\right] - \Phi\left[-\frac{t_{j-1} - \mu_z}{\sigma_z}\right]$$

Thus, the number of vehicles from the entire customer fleet that have mileages between failures is

$$N_j = \left(\sum_{i=1}^k S_i\right) P_j$$

Now, returning to the N.I. equation, the counting increment for the j^{th} failure mileage is

$$NI_j = \frac{(n+1) - (ON_{j-1})}{1 + [n - (\sum_{i=1}^j N_i)]}$$

where

ON_j = the j^{th} failure order number

NI_j = the counting increment applied at the $(j-1)$ failure to obtain the j^{th} order number

The denominator is the number of vehicles beyond the present suspended data set, which equals the total number of vehicles sold (n) minus the number of vehicles with mileages below the j^{th} failure ($\sum_{i=1}^j N_i$). The failure order number for the j^{th} failure is then

$$ON_j = ON_{j-1} + NI_j$$

The estimate for $F(t)$ at the j^{th} failure for this application is simply taken as

$$R_j = ON_j/n$$

With the rank values and the failure mileages, the Weibull failure distribution can be estimated at least two ways. First, the data can be plotted on Weibull graph paper, then a straight line can be drawn through the points producing an estimate of the population distribution from which the data originated. One could then make predictions about the population.

The second proposed method analytically estimates a straight line through the calculated data points by using weighted least squares. This method is explained in [7].

CONCLUSION

The approaches presented in this paper are very elementary and many other considerations should be incorporated. For example, some customers will be lost at the end of the warranty period which terminates on mileage or age. An approach is needed for measuring and handling this consideration. Also, other basic approaches such as the use of nonparametric models [6] should be explored.

Automotive reliability estimation presents unique problems, and it is hoped that others will be encouraged to continue research in this area. Ultimately, a good measure of product reliability is an advantage to a company in that it indicates product weaknesses and also, over design. Through this knowledge a better product can be provided at a reduced cost.

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COMPARISON OF BURN-IN AND LIFE TEST GROWTH MODELS

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INTRODUCTION

In 1962 J. T. Duane of General Electric postulated that as long as a continued reliability effort is maintained that cumulative failure rate and cumulative hours will plot as a straight line on log-log paper. His thesis was supported by five sets of data obtained during the developmental test phases.

Since that time a number of papers have been published on various aspects of growth modeling utilizing the basic Duane model. Papers have been presented on the basic usefulness of the Duane Model (2, 3, 4, 7, 9, 12, 13), the relationship of the Duane Model to the Weibull failure rate function (7, 8, 12), methods of estimating parameters (1, 5, 6, 8, 10), and techniques for determining confidence limits for the parameters (1, 6, 8, 10, 11).

The purpose of this paper is to present an application of the Duane Growth Model to equipment which has been design released and in production. A common element of papers cited above is that the data was obtained during development test programs.

Sets of data have been obtained on two lots of different equipment types that are subject to production burn-in tests of 72 hours. Upon completion of the burn-in test, 10 items from a lot were selected for a production reliability acceptance test per MIL-STD-781B test plan XVIII.

A Duane Growth Model was fitted to the data and projected to the end of the reliability acceptance test. This enabled management to determine whether the equipment had a reasonable chance of passing the reliability acceptance test. Both examples resulted in reasonable projections which were later compared to Duane Growth Models calculated for all test data through the reliability acceptance test.

Duane Growth Model

The following formulation for the Duane growth model has been used in this paper.

$$m(t) = m_0 t^{\beta}$$

where

m_0 = the intercept value of the MTBF (log m at log t = 0)

β = the growth slope

$m(t)$ = Cumulative MTBF at time t

t = test time/equipment or equipment age

The cumulative MTBF is based on the total test time and failures on all equipments of the burn-in test.

$$m(t) = nt/F$$

where

n = number of equipments

t = test length

F = Total number of failures on all equipments

The major difference in this formulation compared to the applications of the growth model to development test data is in the definition of "t". For development test data "t" is the cumulative test time. However, for burn-in data it is more appropriate to define "t" as the equipment age.

This model can be used as a tool to predict the possible outcome of a production reliability acceptance test based on the acceptance criteria, number of units on test and equipment age at the start of the test.

The parameters m_0 and β were calculated using a weighted least squares technique. Each failure is weighted by its failure number, F_i ; each failure is plotted as though it occurred F_i times at that point.

$$\beta = \frac{\sum F_i (\sum F_i \log t_i \log m_i(t)) - (\sum F_i \log t_i)(\sum F_i \log m_i(t))}{\sum F_i \sum (F_i (\log t_i)^2) - [\sum F_i \log t_i]^2}$$

$$\log m_0 = \frac{\sum F_i \log m_i(t) - \beta \sum F_i \log t_i}{\sum F_i}$$

This method gives greater weight to the most recent data, which in reality is cumulative and contains all previous data.

An estimate of the current MTBF ($M(t)$) of the equipment is obtainable from the Duane model by the following equation.

$$M(t) = \frac{m_0 t^\beta}{1 - \beta}$$

EXAMPLE A

This example consists of 59 items, each of which was subjected to 72 hours of burn-in. After completion of burn-in, 10 items were selected for a reliability acceptance test per MIL-STD-781B Test Plan XVIII. This test plan is a fixed test length of $9.4\theta_0$, with an accept decision with 13 or less failures.

The data of the burn-in test is given in Table I. The following results were obtained:

Total Burn-in Test Time = (59) x (72) = 4248
 Number of Burn-In Failures = 18
 Observed Cumulative MTBF 236

The required MTBF (θ_0) for the equipment was 800 hours.

Total Reliability Acceptance Test Hours = 7520

Projected Number of Failures $7520/236 = 31.9$

Since passing the acceptance test required 13 or less failures, this simplified analysis would make it appear that there was absolutely no possibility of passing the test. The purpose of a burn-in test is to eliminate early failure mechanisms and a decrease in failure rate is to be expected. The parameters of the Duane Growth Model for this set of data are given below and plotted on the figure for Example A.

$$\beta = .326$$

$$M_0 = 40.29$$

In order to project the expected number of failures, we note that the ten systems will enter the reliability acceptance test with 72 hours of operation and end with an additional 752 hours for a total of 824 hours. To determine the number of failures per equipment, we calculate:

$$m(72) = 162.4 \text{ hours} \pm .44 \text{ cumulative failures}$$

$$m(824) = 359.6 \text{ hours} \pm 2.29 \text{ cumulative failures}$$

The expected number of failures per equipment is $2.29 - .44$ or 1.85 failures during the reliability acceptance test. For 10 equipments we expect 18.5 failures; considerably less than the 31.9 projected without the benefit of a growth analysis. If we assume Poisson, the probability of 13 or less failures is approximately 12%.

After completion of the reliability acceptance test, during which 9 failures occurred and an accept decision made, a Duane Growth Model using both the burn-in data and the additional data obtained from the reliability acceptance test was applied. This data is presented in Table 2. The parameters of this Duane Growth Model are given below and plotted on the graph of Example A.

$$\beta = .351$$

$$M_0 = 38.1$$

The burn-in data appears to have under-estimated the growth rate resulting in a slight over-estimate of the expected number of failures.

EXAMPLE B

This example consists of 49 test items, each subjected to burn-in of 72 hours, with 10 items selected for a reliability acceptance test with $\theta_0 = 1200$ hours.

The data of the burn-in test is given in Table 3. The following results were obtained:

Burn-In Test Time = (49) x (72)	=	3528 hours
Number of Burn-In Failures	=	14 Failures
Observed Cumulative MTBF	=	252 Hours
Total Acceptance Test Hours	=	11,280 Hours
Projected Number of Failures		
11,280/252	=	44.7

The conclusion of this analysis is that passing a reliability acceptance test with 13 or less failures would be highly improbable.

Utilizing a Duane Growth Model similar to Example A, we obtain for this set of data

$$\beta = .483$$

$$M_0 = 23.6$$

This line is projected on the graph for Example B. The following is the projected number of failures, where each item will have 1200 hours of operating time at the end of the acceptance test.

$$m(72) = 186 \text{ hours} \pm .39 \text{ cumulative failures}$$

$$m(1200) = 725 \text{ hours} \pm 1.65 \text{ cumulative failures}$$

The expected number of failures per equipment during the reliability acceptance test is $1.65 - .39$ or 1.26 failures or for 10 equipments we obtain 12.6 expected failures. If we assume a Poisson we would project a 60% chance of passing the reliability acceptance test.

In this case 9 failures occurred during the reliability acceptance test, resulting in an accept decision. Table 4 gives the combined data for the burn-in data and the reliability acceptance test. The following Duane parameters were obtained and plotted on the graph of Example B.

$$\beta = .434$$

$$M_0 = 29.3$$

TABLE 1
EXAMPLE A - COMPARISON OF OBSERVED AND DUANE
MODEL CUMULATIVE MTBFS OBTAINED DURING BURN-IN TEST

EQUIPMENT AGE -HOURS	CUMULATIVE EQUIPMENT HOURS	CUMULATIVE EQUIPMENT FAILURES	OBSERVED CUMULATIVE MTBF	DUANE CUMULATIVE MTBF	DUANE CURRENT MTBF
8	472	6	78.7	79.4	117.8
16	944	8	105.5	99.5	147.6
24	1416	13	108.9	113.6	168.5
32	1888	16	118.0	124.7	185.0
40	2360	17	138.8	134.1	199.0
48	2832	18	157.3	142.4	211.3

TABLE 2
EXAMPLE A - COMPARISON OF OBSERVED AND DUANE
MODEL CUMULATIVE MTBFS OBTAINED DURING BURN-IN TEST
AND EXTENDED THROUGH PRODUCTION ACCEPTANCE TEST

EQUIPMENT AGE -HOURS	CUMULATIVE EQUIPMENT HOURS	CUMULATIVE EQUIPMENT FAILURES	OBSERVED CUMULATIVE MTBF	DUANE CUMULATIVE MTBF	DUANE CURRENT MTBF
8	472	6	78.7	79.1	121.8
16	944	9	105.5	100.8	155.3
24	1416	13	108.9	116.2	179.0
32	1888	16	118.0	128.6	198.1
40	2360	17	138.8	139.0	214.2
48	2832	18	157.3	148.2	228.4
80	4139	20	206.9	177.3	273.2
88	4227	21	201.3	183.4	282.6
96	4323	22	196.5	189.1	291.4
104	4414	23	191.9	194.5	300.0
160	4974	24	207.2	226.2	348.5
400	7374	25	294.9	312.0	480.7
584	9201	26	353.9	356.3	549.0
800	10801	27	400.0	397.9	613.1

TABLE 3
EXAMPLE B - COMPARISON OF OBSERVED AND DUANE
MODEL CUMULATIVE MTBFS OBTAINED DURING BURN-IN TEST

EQUIPMENT AGE -HOURS	CUMULATIVE EQUIPMENT HOURS	CUMULATIVE EQUIPMENT FAILURES	OBSERVED CUMULATIVE MTBF	DUANE CUMULATIVE MTBF	DUANE CURRENT MTBF
8	392	5	78.4	64.5	124.8
24	1176	12	98.0	109.6	212.0
48	2352	13	180.9	153.2	296.3
56	2676	14	191.1	165.3	319.7

TABLE 4
EXAMPLE B - COMPARISON OF OBSERVED AND DUANE
MODEL CUMULATIVE MTBFS OBTAINED DURING BURN-IN TEST
AND EXTENDED THROUGH PRODUCTION ACCEPTANCE TEST

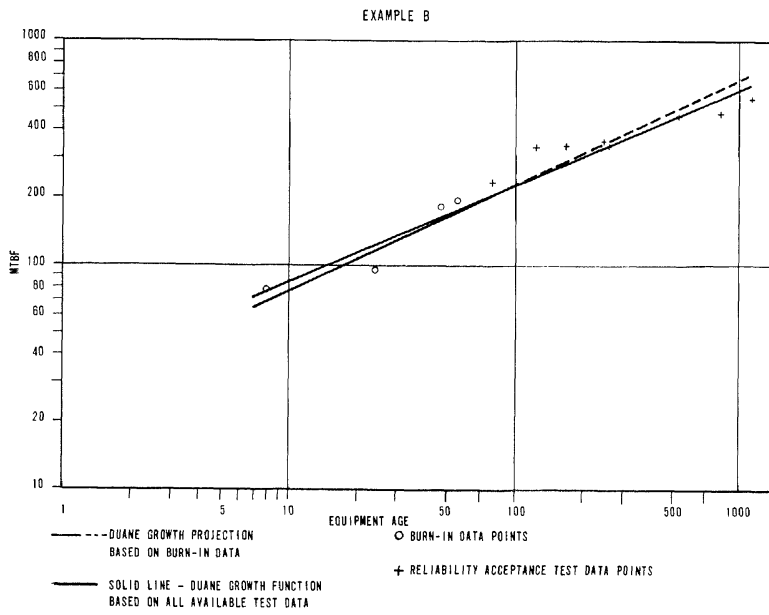
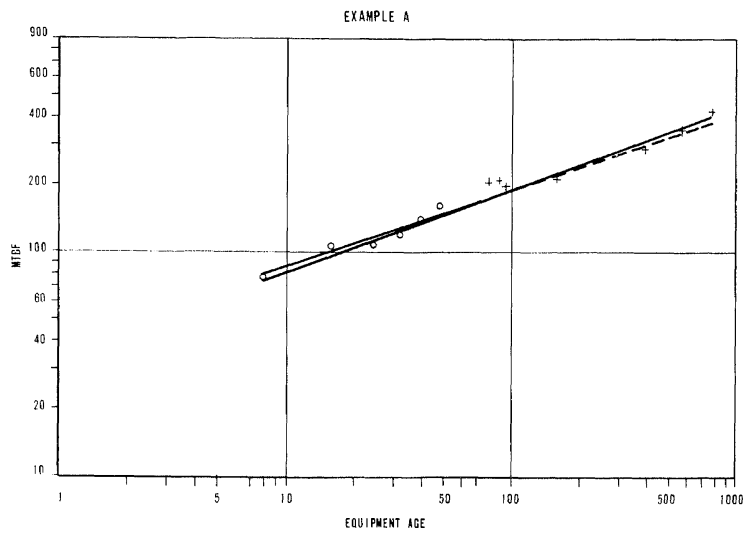
EQUIPMENT AGE -HOURS	CUMULATIVE EQUIPMENT HOURS	CUMULATIVE EQUIPMENT FAILURES	OBSERVED CUMULATIVE MTBF	DUANE CUMULATIVE MTBF	DUANE CURRENT MTBF
8	392	5	78.4	72.3	127.7
24	1176	12	98.0	116.8	206.0
48	2352	13	180.9	157.3	277.9
56	2676	14	191.1	168.2	297.2
80	3449	15	229.9	196.3	346.8
128	5181	16	323.8	240.8	425.4
168	5581	17	328.3	270.9	478.6
248	6321	18	351.2	320.8	566.8
264	6481	19	341.1	329.6	582.3
536	9201	20	460.1	448.2	791.8
544	9281	21	442.0	451.1	797.0
816	9694	22	440.6	537.9	950.3
1116	12627	23	549.0	616.2	1088.7

CONCLUSION

Both examples have shown that the Duane Growth Model applied to burn-in data will obtain reasonable results when used to project the probability of passing reliability acceptance tests. The assumption of continued growth during the reliability acceptance test seems to be justified in the two examples presented.

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A FMECA'S USE -- BY WHOM AND HOW

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INTRODUCTION

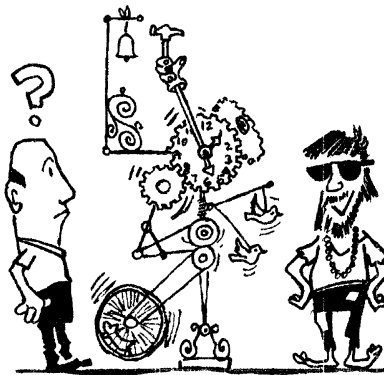
We all know what is required in a FMECA, a Failure Mode, Effects and Criticality Analysis. We have seen many types of formats. Most of them have headings similar to the two examples shown in Table 1.

Table 1. FMECA Format Headings

Example "A"	Example "B"
Identification Name/Number	System Model
System Name/Number	System Name/Number
Part or Assembly Number	Component Name/Number
Cause	Reported By & Date
Failure Mode	Revised By & Date
Effect of Failure	Item Number
Hazard Classification	Function
Remarks	Failure Mode
	Primary Effect
	Design Philosophy
	Method of Detection
	Hazard Classification
	Failure Rate per Mode
	Failure Rate Summary
	Approvals

The fact that we have been required by contracts and specifications to provide detailed studies of each part is very much old hat to most of us.

The use of a FMECA, in my opinion, has changed. FMECA's have gone from: "Fictitious Material Easily Cataloged Ashcan" or maybe "For Management, Extra Costs Accumulated" to "Factual Material Easily Compared to Actuality". This change in the importance of the FMECA has been brought about, at least in the military aircraft accessory industry, again my opinion, by the ever increasing emphasis for the "big R - easy M" -- maximum reliability with a minimum of easy maintenance. And, I believe that the increased emphasis placed lately on product liability in the commercial industry has placed more rather than less importance on the use of the FMECA.

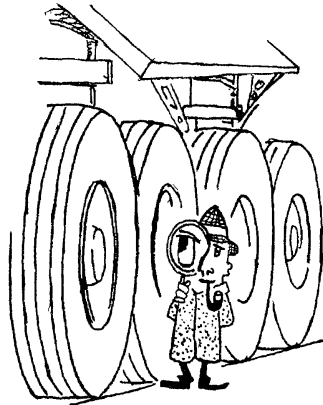


It is the purpose of this paper to describe some practical, day to day ways in which the FMECA's use can be upgraded to meet this increase in need. At least, to present ways which have helped me. These ways involve who produces the FMECA's, who uses the FMECA's and how they are used.

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CUSTOMERS USE FMECA'S

It is a known fact that customers want a "warm feeling" about our product's ability to operate satisfactorily long enough to meet contract requirements -- not just long enough to get out of the warranty period-- but through years of service life as well. Words like "design based on past experience" or "designed by a leader in the industry for the past 25 years" haven't cut the mustard in FMECA's like they might have in the past years. Management teams have been demanding design PROOF that the products have actually been designed, not just put together. It is a known fact that customer "A" is well aware of the major problems you have been having with customer "B". And, customer "A" expects proof that the design for him has actually addressed and has corrected past problems like those of customer "B" with effective changes and corrective actions.

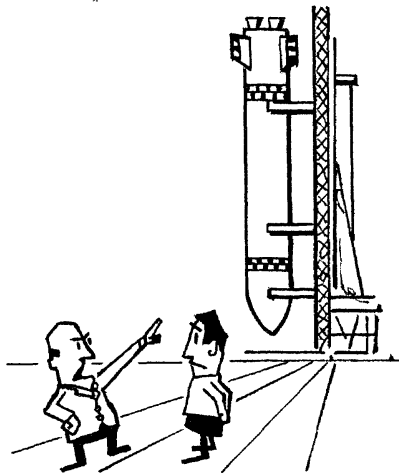


FMECA reading is dry work. Work that few people have had-or have taken the time necessary to accomplish the task adequately. But, I am convinced that the customers have read them. Especially when a problem has happened. Among other things, they want the answers to questions like: "Was it considered in the FMECA?", "How did you design it this time to prevent that type of problem?". These questions come almost on top of the usual ones like: "What are you doing about it?", "When will it be fixed?", and, "How many more like that one have you already slipped past me?".

So, maybe I have convinced you that customers want from this report the warm feeling that our companies designed the device. Designed them from design policies and have it all documented. And, they expect the assurance that the documentation is easily retrievable, not buried away in three or four designer's notebooks, scratch pads, or in a waste basket somewhere. I have found that the FMECA is that documentation to provide this type of assurance. But, does anybody else use it? They sure do,-- that's my answer. Or, at least, they sure should. And, I maintain, they sure can if the FMECA is done practically.

DESIGN ENGINEERS USE FMECA'S

Since design engineers have been given copies of the FMECA's -- and have read them, some definite improvements have been made in the designs. Improvements that were made at a time in the program when all it took was an eraser,--and maybe 10 hours plus about a week's slip in the delivery schedule --but it is the cheapest point in the ball game to catch an oversight. When the FMECA indicated that the part "may be assembled backwards", sometimes a light came on in the designer's mind of a way in which he was able to alter the design and prevented it from being assembled backwards. It might just be that the designer was actually convinced that whoever it was that wrote down "Corrosion" as a possible cause for a failure was a person who had actually experienced such a cause for a failure on one of the past designs to the point that it was of major concern to him. And more attention was



actually paid to the manner in which he was really trying to prevent corrosion on this new design. Therefore, maybe a better way was used.

After seeing "external fuel leakage" as an effect for one "O" ring after another, around the outside of his beautiful design, the designer, the sole owner of the eraser, sometimes actually found a way to eliminate a few of these kinds of parts-- or the parts that required the "O" rings for that matter. I know, designers are like most of the rest of us. They do not like to have their work questioned. But, when they realize that the FMECA is an honest attempt to help them to prevent past problems from turning up once again on new designs, they have looked upon this tool of management in a somewhat different light.

INSPECTION ANALYSTS USE FMECA'S

Many times in the past, when I wrote FMECA's, I knowingly indicated -- in the area of the FMECA sheet explaining why this part will never fail that way -- that "Inspection will check it, Quality will catch it, pressure test it, verify that the operation has been done properly and checked". And, chills went up and down my spine. My gosh, will they -- really? How can I be sure that somebody even knows (-or cares-) that I am telling our customer this. It was soon clear that we had better get a copy of the FMECA for the Inspection Analysis Manager, also. But, then maybe - way back then - I had conversations like:

"What's this for?"

"You expect me to read that 'Manhattan phone book' of a thing?", or, ---

"Oh, yea, thanks. I'll get around to reading it when I can find the time."

Maybe you have had some conversations like that, too.

They previously didn't know what a FMECA was. They didn't know what was in it that will be of benefit to them. They didn't know how to use it. Maybe one or more good ideas from the FMECA might pay back a whole lot. It was agreed that they should be told (and convinced) that it was to their benefit as well as the company's benefit for them to actually USE it. There are ways to help them to use it, but before going into that group of suggestions concerning ways we have found to organize a FMECA so that they actually help the users, permit me to discuss two more major users (and uses) of the FMECA.



ASSEMBLY PROCESSING'S USE OF FMECA'S

A group of people at our plant write out detailed instructions as to how each part is to be assembled and where. Great big thick books--for large fuel controls that are very complicated-(in that they have lots of parts, I mean). Full of pictures, sketches, arrows, instructions, and the like. It was realized that this group should know that if this tiny cotter pin wasn't properly assembled and spread that it could bind up on the adjacent part. These are the people who make up the check sheets or something like that to make sure that all of the taper pins have been put in and that they are all properly spread because if one of them falls out all sorts of problems may start to happen.

Oh, sure, this is very routine stuff. Even without the FMECA. Not a thing new about that. But, it was found that this group was more concerned about these special instructions and cares after they had some way of knowing the major consequences of these routine operations if they might accidentally be done improperly. Again, they became convinced that these

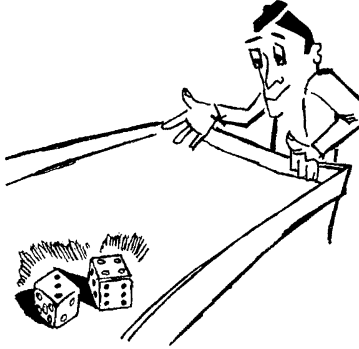
undesirable events have most likely happened before -- at what expense God only knows -- and they were more likely to heed the warnings of the FMECA, and heed them more firmly than before they knew that the FMECA was in existence or before they used it.

RELIABILITY ENGINEERING USES FMECA'S

"Naturally", you say. "Didn't they write the thing in the first place?" Yes, no doubt they did. But, I maintain that this task only started the ball rolling. Now, they should use it as well.

It has been found very productive to use it to track actual failure reports back to the individual piece parts, the item(s) in the design that caused the problem in the first place. Also use it to upgrade failure mode lists, to find out actual failure rates for the same kinds of parts used in different applications. Benefits are possible by proper organization of the FMECA so that it can be used.

Published failure rates by various standards, handbooks, etc., seem to be loosing favor with the military and customers of the military. They are no longer accepted at face value as a good source of failure rates. Actual experience sometimes is too far from the anticipated failure rate. Designs estimated from such "Cookbook" values don't seem to come up to expectations concerning the failure rates like they should have. It seems that what is wanted is YOUR ACTUAL experience with these parts, YOUR records, YOUR failure rates. That seems to be what really counts.



This is great if you have the data already. Maybe electronic device manufacturers have such data. I don't believe that very many of the hydromechanical device manufacturers are very far along this road yet when it is the specific part type, part application -- as you use it -- that is what is desired. I have found that the FMECA is one way of logging or cataloging failures so that factual failure rates can be provided. But, it is murder to go back to the file drawers and try to pull that kind of stuff out of the past field service reports, quality investigation results, wires, etc. Yet, it has to start sometime. No better time than your next FMECA, you next new contract. Having a copy of the FMECA organized by part number, another copy organized by part type, and still another copy by functional groups as well as the copy set up per the Bill of Material setup will be found to be most useful, I am sure. With these, it is much easier to catalog actual failures on the back of the appropriate FMECA sheets, with the dates, and the other reference data you may need to get back to the actual facts. Now, with this kind of data organization, you can get factual failure rate data at any point in the program.

After all, since the FMECA can be organized by part number and also by part type, all we need to know to play the failure rate game is the amount of test time in the time period being studied. If every hour of time means 50 "O" rings get tested, 20 springs, 5 bellows, 15 brazed joints, etc., then we can begin to get an idea of part type failure rate from our own data. If we know that it was a failure of a brazed joint that caused the malfunction, how about that -- we are even getting process failure rates. Now, we are getting somewhere. With data like that the statisticians can have a field day with point estimates, 90% confidence intervals, growth curves, and the like. With that kind of data we can develop our own cookbook of failure rates. And, isn't that just exactly what our customers have been wanting us to do all along? I am of the opinion that the FMECA organization is a very good place to start.

WHO DOES WHAT

The message of this paper was drastically altered by a question I was recently asked after my abstract was prepared and submitted for the review. The question was "Who uses the FMECA if the Design Engineer does not?" I hope that the discussions just completed have helped to answer that question. I hope that my ideas might be found to be helpful to you. But, another part of my answer concerned who writes FMECA's. My answer to the above question included the statement that Design Engineers should WRITE a major portion of the FMECA as well as use it, with Quality Assurance doing the rest.

So, if you are still with me, let me take a few minutes to pass on to you my suggestions on the who, what, and how of FMECA writing and organization, as I have seen it from our needs and our own point of view.

ORGANIZE FMECA'S FOR USE

The FMECA has to be organized in such a manner that it is a ready tool to assist in answering such questions as "How many external plugs & "O"rings in this thing could cause an external leakage of fuel due to being damaged at assembly?" "How many external plugs are pressure tested to 100-150% of the maximum operating pressure in the hole closed by this kind of a device?" The answers to these questions are expected from the Quality Assurance and Reliability Engineer many moons after the design calculations have been made. The FMECA is the major candidate as to where to document the answers to these questions so that the answers can come within a few hours, not days or weeks, or never.

These answers, and others like them, have been found much easier to get after the FMECA has been presented by part number, one part number to a page. Copies of the FMECA can then be arranged, as stated earlier, by the part number, type, functional group or any other way desired. When several items are discussed on one page, or a subassembly is talked about in only general terms, it becomes much more difficult to hunt for the answers.



WHO STARTS -- WHO FINISHES

What do I mean by "start". Start the FMECA by identifying each part on the sketch, schematic diagram, or layout. Castings, threaded inserts, soldered joints, cotter pins, sliding fits, etc., each and all must be identified. This may be much more difficult to do from a schematic diagram, but if it is on the schematic diagram, it no doubt is critical or at least important to the operation of the device. I know you have heard it at least twice before, but use one FMECA sheet per part number. Start by filling in the part name, identification number or something so that you will be able to track the FMECA sheet back to the schematic diagram. Put in the most likely failure modes and the possible causes. Maybe even take a stab at the primary effect. "Most likely", to me, means three (3). Three types of problems that have actually occurred and have occurred most frequently in the past on similar products with the same types of parts. If only one such problem exists, or even no problems at all, -so much the better. Say so on the FMECA sheet. Let it be known that, in your opinion, no problems have been reported based on actual experience-yours or your company's. But, forget about the fifteen (15) or so failure modes that you could think up that might just possibly happen.

OK, start has been defined. So, who starts? From my point of view, the Quality Assurance Engineer starts. After all, if the Quality Engineer doesn't know what the past problems have been in the inspection, assembly, test, customer's plant and field service areas, at least he will know who to ask. Then, feed these sheets to the Design Engineer. At least, that is our way. And, one plea, request, mandate, or order to: "Give me facts, man."

"What facts?"

"Design for reliability facts."

"What does that mean. All of my designs are reliable."

"I never designed anything to bust."

"No, but sometimes they did. How come?"

"Well, nobody told me about them. I can't be expected to be a mind reader. Why didn't somebody tell me about them, sooner."

How sweet it is to be able to now go to the design engineers with the FMECA sheets and NOT get that kind of a response. You see, the design engineer must be convinced that he should "do his thing" with his design calculations, etc., and "that thing" is to put them into the FMECA sheets so that his data becomes a part, a very major part, of the overall picture that is being painted by the FMECA to give that customer the "warm feeling" he needs to decide on your company as a winner.

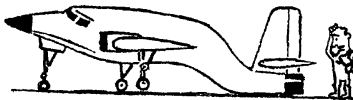
DOCUMENT ALLOWABLES

Not many of us, I don't believe, have gotten to the full use of the theoretical approach of designing for reliability, where the "nines" come out of the calculations like popcorn. But, we must know from the drawings what the actual stress is going to be in a part, like a spring. This is part of the picture. What the design engineer knows, in addition to this data, is that this stress is actually only 86% (or some such number) of the allowable stress usually used for this application by your company. But, unless he (the Design Engineer) tells somebody that, there is hardly any way to really be comfortable that it actually won't fail due to the stress that he said was going to be in the part. We need to tell the customer the allowables, as well as the actuals. Tell him in the FMECA. Stress, deflection, load, volume fill, percent squeeze, torque, you name it. Factors of safety, margins of design, fatigue ratios, are the kinds of data needed from the design engineer when he fills out the rest of the FMECA sheet.

I am sure that you are familiar with some of the text books that have been written on the subject of designing for reliability. Actual design criterias have been developed by probably every company designing products. Some of these policies or criterias are public, some are your private property. I don't think that it is necessary to give away the barn in the FMECA, but, I do believe that it is necessary to provide the assurances that the designs have been checked against your standards and acceptable to them. These design policies have been needed for review, at least, by customers, at various times during a contract.

WHEN A FMECA IS USED

The last of the who, what, how, why and when is when. When to use a FMECA. At design reviews, naturally. But, we have found that it can be used at many more places, at other times than just there. I have attempted to tell you about a few of them by means of this paper. Benefits have been made from FMECA's. It is my opinion that more benefits can be obtained from them.



It is hoped that the ideas presented in this paper, basic as they may be, have at least started you thinking of ways you and your company can get more use from FMECA's, by whom, and how.

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LCS 840:70:437

TESTING FOR PRODUCT LIABILITY

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HISTORY - WE CAN DO IT

Product liability is new, however, product testing has been with us for a long time. The most sophisticated testing and evaluation started in the aircraft industry which included test pilot evaluation with some pre-flight safety testing. As the aerospace industry became more sophisticated and some systems no longer had test pilots, the Pre-Flight Rating Test (PFRT) began to include expected environments. Our early missiles were designed to a model specification, tested to an acceptance test, qualified for environments to a Qual Test Specification and then safety considerations at various environments were investigated during the Pre-Flight Rating Test. With all of this our early missiles failed and the requirement for reliability was identified. Then after the pilot-tested DC-3, reliability was transferred to Minuteman calculate reliability technology. The aerospace industry proved that good drawings and change control were necessary to assure what was tested matched what was furnished. In order to increase the price of aerospace equipment, the aerospace industry convinced the Department of Defense that good drawings and control was a new science called Configuration Management. In commercial products the computer industry has done the best job of assuring performance partly by design and secondly by specifying the environment of use. There is little doubt that both a reliable and safe product can be furnished to the consumer. The industrial technology and techniques of evaluation are available to industry.

- INDUSTRIAL BEHAVIOR -

Product liability laws have changed the pressure points and industry is now trying to get organized to deal with the problem.

Many consumer demands are unreal, however, many industries are still working without good drawings and operational knowledge of what they produce.

The most advanced industry may well be the toy manufacturers. The pressure is currently being placed on bicycles and skateboard manufacturers. And the most stubborn is the automotive industry who has not responded since 1950, when we first saw smog, without daily fights and pressure delays in dealing with Congress. It is difficult to fault the automotive industry in design control, quality control or the product they provide. However, the automotive industry has created considerable problems with smog, and if they were not so big and wealthy, they would have to solve the automotive exhaust problem.

On the other hand, the manufacture of football helmets is treated unfairly. No claims come from the professional ranks where trainers maintain the equipment and fit the proper size. Most claims come from the high schools who think the reason for helmets is to identify the team's color and each player should have one.

- SOME INTERESTING PROBLEMS -

Products manufactured should have some statute of limitation for products sold. Being held to the best known technology of the current day as the standard for products manufactured in the past is unreasonable. The National Product Liability Council, working on product

liability legislation, identified four major difficulties:

1. First, there is no statistical proof available to prove in terms satisfactory to a crisis oriented Congress, that there is, in fact, a crisis. The reason, to anyone who has been involved as a buyer of large volume of insurance, is very simple. In product liability claims, in addition to the fact that a product may have been in existence many, many years before an injury occurs, it is normally eight to ten years before ninety percent of claims occurring within a year are paid. In other words, it will be 1985 or 1987 before the 1977 claims are ninety percent paid. Insurance companies and insurance rating organizations are just not geared to make predictions of this nature for many reasons which are not the subject of this paper today.
2. Second, there are strong entrenched special interest groups, which at every opportunity, cloud the issues. One such group, attorneys engaged in the injury business, blame the insurance industry. Another such group, the insurance industry, blames the manufacturer, pointing out that a manufacturer should have a strong safety program and that there are some products that underwriters today just don't believe deserve, in their mind, to be manufactured.
3. The third hurdle, in our opinion, is that industry and business in general, has a bad public image. As consumers, all of us in industry are enjoying a life which is better than that of a millionaire of a mere one hundred years ago. Yet, it appears that in our capacities as consumers, we give little credit to the success of American industry in making all of this possible.
4. The fourth difficulty is that any diversity of opinion that industry may have among itself will only be used by the special interest groups to stall and defeat a bill. We need, if at all possible, a unified approach that we can believe in as consumers, and not one that sounds like a special interest approach.

- REDUCING THE RISK -

Product liability has had several major impacts on industry. Leisure time products were high on corporate acquisition lists. Now, due to many consumer claims, many corporations are selling off leisure groups. The development of new products is being restricted if there is any sign of product liability exposure. Most corporations involved in mergers and acquisitions check very closely on past product liability claims and increases in insurance renewal rates. The reaction to products with high product liability risk is to quietly move them aside. This will develop two basic problems for the consumer-higher cost and difficulty in obtaining such products.

Insurance companies will take more interest in the evaluation of manufacturers. They will look for quality control programs which minimize the chance of product failure. It is expected that design reviews will be completed to assure consideration for product safety and reliability.

- LOOKING AT NEW METHODS -

The transfer of technology in materials, processes, design concepts and product evaluation has generally followed from the aerospace industry to other industries. In product liability, other industries can now look to the toy industry for leadership. These designs have always been high on misuse, no maintenance and frequent drops. It has been ten years since the lady called the quality control manager of a leading toy company to ask for a new set of instructions because her daughter ate them. As the quality control manager laughed and

offered a new set of instructions, she completely wiped the smile off his face with a simple question: "Do you know if the ink or paper could be poisonous?" This was a true surprise and concern that to most quality control managers had nothing to do with the product.

The toy industry has developed product qualification practices by watching children play with toys through one way mirrors. Close attention is given to noise, temperature, color, size, weight and, above all, product safety. Sharp edges and points have been eliminated and the total product is qualified to include unexpected ideas of the user.

- NEW PRODUCT DEVELOPMENT REQUIREMENT -

Each phase of the product life cycle (i.e. research, development, design, production, operation and disposal) requires specific tasks to be completed. In research each task is investigated on its own merit and a bank of knowledge is collected and catalogued for possible use. The development phase basically identifies a need and matches methods and combinations to develop a product concept to serve a specific need. In the design phase, product is completely identified and tested to assure proper operation. Testing is then extended to include proper operation in each environment (i.e. life, temperature, salt spray, humidity, vibration, shock, sand, dust, rains, sunshine, etc.) in which the product is expected to operate. The design phase is completed when the product has been completely identified and qualified by test for each environment. The production phase requires a complete check of the drawings and inspection of the hardware to assure complete compatibility. Any changes in the design should be completely requalified and the product definition should be continuous so that each configuration can always be included in the active drawings and technical data package. The definition and hardware must always match with all non-conformances controlled. As the product enters the operational phase the manufacturer is required to provide spare parts and assure that they are available. The user has to be trained for proper operation. Both the manufacturer and user must work together in developing a maintenance plan and operational system to assure proper equipment utilization. Nuclear systems have now made us more aware of the disposal phase. We cannot store nuclear waste in junk yards like old automobiles. The above sequence is followed for appliances, aircraft, boats, farm equipment, consumer products, trains, ships and nuclear installations. The big problem is scheduling and completing each phase in the proper sequence.

Product liability is adding a new requirement: safety considerations for failures and wearout. Wearout and failures can no longer cause side affects which are unsafe. The manufacturer is responsible to control conditions and environments during problem periods. The user must assure safety of removal, repair, installation and putting the equipment back in operation, however, if he has any problem, you can be sure the manufacture is responsible.

PROCUREMENT QUALITY ASSURANCE OF P C BOARDS

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First, I would like to position MICRO SWITCH for you and give you some idea of why quality printed circuit boards are so important to us. The precision snap action "Micro Switch" was invented in 1932 by an employee of the C. F. Burgess Battery Company of Freeport, Illinois. MICRO SWITCH began as a company as a spin-off from Burgess in 1937. The small precision snap action switch was a technological breakthrough that led to a lively industry. The company became a division of Honeywell in 1950 and our catalogs today list over 30,000 different switches and industrial controls. We employ over 3,000 people in and around Freeport, and have additional plants in North Carolina and Massachusetts. We also have manufacturing facilities in Canada, Scotland, Germany and Japan.

The 1960's were the era of pushbuttons for switch manufacturers. In 1964 MICRO SWITCH introduced a mechanical code generator that we named the KB switch. In 1966 the KB switch was modified by substituting the reed switch for mechanical contacts. In that same year MICRO SWITCH began building custom keyboards using reed capability.

But customers kept asking for more wiring and more encoding to meet their hardware needs. Our high construction costs were discouraging. After extensive market research we decided to enter the market as a full keyboard supplier. We made that decision because we believed prices for electronic keyboards (then about \$250) were too high, and because we had just experienced the second breakthrough in the 35 years of our history. This breakthrough was the conversion of the Hall effect (known since 1879) into an integrated circuit chip complete with trigger circuitry and amplification. In other words, our engineers created a bounce-free electronic switch, compatible with nearly all forms of solid state logic, that would operate at a rate of 100,000 times per second and offered nearly infinite life because actuation was by a magnet, which never even touched the chip. Price of this solid state keyboard? About \$100. Price is still under \$100.

Today MICRO SWITCH is probably the largest non-captive maker of electronic keyboards in the world. Which makes us a large consumer of printed circuit boards, primarily for keyboards, but also for our photoelectric and proximity switch lines. Making sure that MICRO SWITCH keyboards were as reliable as possible led to the invention of some award-winning computerized test equipment, a one per cent AQL and the only two-year warranty in the keyboard business. It also led us to the sin of over-specing printed circuit board requirements. This is how we approached this problem.

Our investigation started as a result of the excessive number of non-conforming lots of purchased printed circuit boards being received at MICRO SWITCH. The objectives were to reduce the overall percentage of defects and to increase the vendors' awareness of the problem areas.

<u>VENDOR</u>	<u>LOTS RECEIVED</u>	<u>LOTS NON-CONFORMING</u>	<u>% NON-CONFORMING</u>
Vendor A	294	121	41.2
Vendor B	397	155	39.0
Vendor C	48	19	39.6
Vendor D	225	109	48.4
Vendor E	<u>128</u>	<u>88</u>	<u>68.8</u>
TOTAL	1,092	492	45.1

As a result of the high percent of non-conformance shown above, we needed to know the dollar effect of these non-conforming lots, so we ran an analysis of the five printed circuit board vendors vs. all vendors supplying purchased parts. The data was provided by our Monthly Vendor Analysis Report for the eleven-month period.

REPORT PERIOD ANALYSIS (January-November)

1. Number of active vendors in the study	787
2. Number of printed circuit board vendors supplying lots	5
3. Total number of lots inspected	18,621
4. Total number of lots rejected	1,507
5. Total number of lots supplied by the five printed circuit board vendors in Point 2 above	1,092
6. Total number of non-conforming lots supplied by the five vendors	492
7. The cost to process 1,507 rejections at \$40 average rejection cost	\$60,280
8. The cost to process 492 rejections from five printed circuit board vendors	\$19,680

REPORT PERIOD CONCLUSIONS

1. .6% of our total vendors are responsible for 33% of our total non-conforming lots and total cost to process, while supplying only 6% of our lots.
2. The five vendors supplying printed circuit boards average 98 non-conforming lots each or approximately 52 times more non-conforming lots than our overall average vendor who supplied 1.9 non-conforming lots.
3. Due to these non-conforming lots, the average additional cost to process each lot inspected during this period was \$3.24. ($60280 \div 18621$)
4. The average additional cost to process the lots supplied by the five printed circuit board vendors during this period was \$18.02 per lot. ($19680 \div 1092$)
5. It cost 456% more to process material supplied by the five printed circuit board vendors than for our average vendor. ($3.24 - 18.02 \div 3.24$)

To further aid us in this study, we laid out a flow chart of the keyboard processes pertaining to the printed circuit boards. This gave us an overall picture of what is affected by the quality of printed circuit boards as every main step from the vendor all the way through to our final inspection.

A meeting was then held with Production Engineering, Production and Final Inspection supervisors. It was determined that problems encountered in these areas relating directly to printed circuit boards appear to be minimal once the printed circuit boards have cleared through the Receiving Inspection Department.

In the next phase of the study we reviewed the receiving inspection history of the boards in which 27 sequences are checked regularly. A Pareto Analysis was compiled showing the non-conforming defects from the five printed circuit board vendors for the eleven-month period.

SPECIFICATION	PARETO DISTRIBUTION			ACCEPT/DEV.	
	NO. OF DEFECTS	% DE- FECTIVE	ACCUMU- LATIVE %	NO. ACCEPT	% ACCEPT
Hole Size	165	19.0	19.0	150	90.9
Board Dim.	110	12.7	31.7	96	87.3
Cond. Defects	79	9.1	40.8	23	29.1
Gold Thickness	69	8.0	48.8	31	44.9
Plating Visual	66	7.6	56.4	31	50.8
Gold Visual	61	7.0	63.4	27	44.3
PTH Thickness	61	7.0	70.4	10	16.4
Hole Location	56	6.5	76.9	54	96.4
PTH Visual	29	3.3	80.2	16	55.2
Bevel	29	3.3	83.5	11	37.9
Solder Mask	29	3.3	86.8	15	51.7
P/N & Artwork	21	2.4	89.2	20	95.2
Hole Registration	18	2.1	91.3	10	55.6
Gold Adhesion	17	2.0	93.3	1	5.9
Laminate Defects	13	1.5	94.8	5	38.5
Solderability	10	1.2	96.0	6	60.0
Vendor ID & U/L	9	1.0	97.0	5	55.6
Warpage	6	0.7	97.7	5	83.3
Plating Adhesion	6	0.7	98.4	0	0.0
Key Slot Location	6	0.7	99.1	3	50.0
Packaging	5	0.6	99.7	4	80.0
Material Thickness	1	0.1	99.8	1	100.0
Material Identification	1	0.1	99.9	1	100.0
Cu & Resist Removal	1	0.1	100.0	1	100.0
Pattern Registration	0	0.0	100.0	0	0.0
Scratches	0	0.0	100.0	0	0.0
Missing Circuitry	0	0.0	100.0	0	0.0
	868			526	60.6

Nine, or one-third, of these sequences resulted in 80.2% of the defects. In addition, those defects that were accepted on deviations were tabulated for each sequence. The top two defects, hole size and board dimensions, were accepted to "use as is," 90.9% and 87.3% respectively.

Deviations were requested for a total of 868 non-conforming characteristics, of which 526, or approximately 61%, were accepted with no sort or rework required. This showed us that our product definition, i.e., what was specified on our prints vs. what we were accepting, varied to such a degree that none of the printed circuit board vendors could hope to achieve credibility.

This brought us to a point where one of the following steps was required regarding printed circuit boards:

1. Do nothing - and spend in excess of \$21,000 annually processing non-conformance reports.
2. Eliminate inspection of printed circuit boards where accepted deviations exceeded 80%.
3. Review and revise prints and/or specifications to reflect what we have been using 61% of the time.

Management agreed that the first and second procedures were not acceptable and that we could revise our prints to define the requirements correctly. As a result of this agreement, Engineering reviewed the data provided and made substantial changes in:

Increased hole size tolerance range

Increased board dimensions tolerance range

Reduced gold thickness requirements

In addition to the above, we are presently investigating the use of electrical testing of printed circuit boards to cull for shorts and voids.

The final phase of this study was to visit the vendors and to survey the vendors' manufacturing system, process controls and gaging compatibility. We also reviewed their past quality record and in light of the revised specifications, we informed them we would not accept these defects as in the past.

As a result of data obtained from this study, Engineering has revised its requirements. Through the quality survey a better understanding of the vendor's facilities and capabilities was obtained.

Where our total non-conformance was 45.1% when we started our study, the figure for the first quarter of this year is 39%. Although this does not appear to be a significant improvement, if we look at the percentages of change in the "use as is," we find a very appreciable improvement. "Use as is" was running 60.6% when we started, while the figure for the first quarter of this year is 19%. This means that 81% of the non-conforming defects are being sorted, reworked or returned to the vendor and he is being billed for our time. Where we were initially returning 3.9% of the boards we received, the figure now is 11.3%. This is the result of a concerted effort on the part of our Inventory Control and Purchasing Departments to assure that the majority of all products from rejected lots are returned to the vendor. We are only sorting and/or reworking sufficient quantities to meet immediate production needs and returning the balance for the vendor's action. Although the out-of-pocket cost to the vendor of this procedure is probably comparable to the rework and bill-back method, we feel that the vendor's awareness of his own in-plant operations is greatly increased. The vendor's Factory Production and Quality personnel are aware of large inships of rejected material and vendor management is aware of large dollar credits which must be issued on this material. We believe, and our vendors have confirmed, that the need for and the interest level in implementing effective corrective action is heightened through this form of notification. Our early results seem to bear this out.

LCS 351:40:439

TOLERANCES VS. FABRICATION AND COST OF PC BOARDS

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Printed circuit boards, unlike many purchased electrical components, are custom made to a specific dimension and design. There are no printed circuit boards that can be purchased as shelf items in the bare board state. Each board must be built to a specific design determined by the customer. Let me clarify what I mean by a shelf item. A shelf item would be the kind of an item that can be purchased from a dealer or catalog to be used in any number of units. Examples of shelf items are resistors, capacitors, integrated circuits, etc.

Even when end items (calculators, televisions, etc.) are very similar, several manufacturers of those items will have a very different concept of what the printed circuit board should look like. For example, a few years ago, many plants manufactured handheld calculators. The basic calculator needed 10 keys for the functions. They also had to have a display for the numerals. Each manufacturer had these things but the circuit boards were quite different.

The latest item made by many manufacturers are smoke detectors. Here, again, we have each printed circuit board performing the same function, but unique in its design and requirements for each company.

This variation in design and specification can effect the cost of manufacturing the board and hence the price of the board to the customer.

Because printed circuit boards are custom built and have many different requirements, they can be specified many different ways, there needs to be some standards to guide the designers, fabricators, quality personnel and assemblers. A set of standards for printed circuit boards has been developed by the I.P.C. (Institute of Printed Circuits)*. The I.P.C. is an organization of laminate processors, printed circuit board manufacturers and printed circuit board users (assemblers and equipment builders).

In discussing cost related requirements for printed circuit boards, we are going to look at some of the tables and paragraphs of two of the IPC standards.

IPC D300 - "PRINTED WIRING BOARD DIMENSIONS AND TOLERANCES TWO SIDED RIGID BOARDS."

This specification covers dimensioning and tolerance limits based on industry capabilities. It provides five classes for dimensional features to reflect progressive increases in sophistication and cost of tooling, material and processing.

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This specification covers end product workmanship and acceptability requirements for all rigid single and double sided boards and provides classes for workmanship of a printed wiring board that reflects progressive increases in sophistication and cost for tooling, materials and processing.

To give some idea of what is meant by more sophisticated tooling and materials and processing, here are some criteria that can effect the cost of manufacture:

1. Hole Diameter Tolerance

The tolerance could determine if a hole will be drilled or die perforated.

2. Hole Location Tolerance from Datum

May mean a more expensive laminate or require drilling in place of die perforating.

3. Minimum Conductor Path and Minimum Space Between Conductors

This will determine the method of placing the image on the board. Photo resist or screen, and in some cases the size of the panel.

4. Registration Tolerance of Conductor Pattern to Holes

The tolerance required will determine the size of the panel and the method of imaging.

In our shop, the following rules apply:

- (a) $\pm .015$ " registration tolerance will allow us to run a 36" to 38" long panel machine screen.
- (b) $\pm .010$ registration tolerance will restrict the panel length to 18" to 24". Machine screen or handscreen, or we can use a 36" panel then perforate the indexing holes using an optical punch.
- (c) Less than $\pm .010$ to $\pm .005$ will restrict the length to 18". The image will have to be applied by Photo Resist.

5. Workmanship Requirements

- (a) Smooth holes, no crazing or chips; holes must must be drilled
- (b) Smooth edges, no indication of undercut, etc. Board must be finished routed.
- (c) No marks, scratches, blemishes or measling on base laminate. Will not allow the removal of excess copper after etching. Will also require special handling and will increase the scrap ratio.
- (d) No pinholes, nicks or scratches in the conductor pattern. Would necessitate Photo Resist and touch up. Would definitely increase scrap ratio.

The I.P.C. D300 places the various hole tolerances in five classes, Class 1 with the broadest tolerances and Class 5 the tightest.

The presentation in Table 2 is for nominal base material thicknesses up to and including 0.0625. (1,59). For nominal base material thickness over 0.0625 (1,59) and ± 0.001 (0,025) to each tolerance.

TABLE 2 - AS MACHINED; HOLES, SLOTS, AND NOTCHES

FEATURE	CLASS 1	CLASS 2	CLASS 3	CLASS 4	CLASS 5
0/0.032 Diameter	± 0.003 (0,08)	± 0.002 (0,05)	± 0.001 -0.002 (+0,025) (-0,05)	± 0.001 (0,025)	± 0.001 (0,025)
0.033/0.063 Diameter	± 0.004 (0,10)	± 0.003 (0,08)	± 0.002 (0,05)	± 0.001 -0.002 (+0,025) (-0,05)	± 0.001 (0,025)
0.064/0.188 Diameter	± 0.005 (0,13)	± 0.004 (0,10)	± 0.003 (0,08)	± 0.002 (0,05)	± 0.001 -0.002 (+0,025) (-0,05)
0/2.000 Slot or Notch	± 0.005 (0,13)	± 0.003 (0,08)	± 0.003 (0,08)	± 0.003 (0,08)	± 0.002 (0,05)
Ratio of Min. Hole Diameter to Base Material Thickness	2:3 or 66%	1:2 or 50%	3:10 or 30%	1:4 or 25%	1:5 or 20%

[Tolerances indicate total spread and may be varied from the nominal to satisfy design requirements. For example:

± 0.004 (+0,10)
 ± 0.005 +0.006 (+0,13)
 -0.003 -0.002 (-0,08) or (+0,15)
 (-0,05)]

[When radii are not provided in slots or notches, there will be increased cost.]

Let us see what can happen to increase the cost of the holes in a printed circuit board with different tolerances.

Class 1) Unplated holes with a diametric tolerance of ± 0.003 or greater, can be die perforated. Thus, many holes, slots and notches of various sizes can be perforated at the same time (most economical for long runs).

Class 2) Unplated holes with a tolerance of less than ± 0.003 will have to be drilled. Thus, the number of holes and the number of different hole sizes will have a bearing on the price of the board.

Class 3) Unplated holes with a tolerance of ± 0.001 may have to be reamed or at least given very special attention while drilling. Possibly require sorting.

One of the unique characteristics of a printed circuit board that must be specified is the registration tolerance between the conductor land pattern and the holes. This may be done in a couple of ways. The simplest way for the designer, if he disregards all other parameters, is to specify a minimum annular ring. The minimum annular ring is the amount of metal land left around the hole on the narrowest side. When the designer so specifies, sometimes it becomes very difficult for the fabricators to process the board as was intended at the time of quotation or layout. It could mean he has priced the board to a certain process and then discovers he has to go to a more lengthy process thus increasing the cost of manufacturing. This, of course, would also increase the price of the board. Even when the full land size is considered in relation to the hole size with the necessary tolerance to build the board economically.

The designer may have to shave pads for electrical spacing requirements, and unless the annular ring requirement is waived in that area, the quality control department is sure to (a) stop the

job, (b) reject all product produced or (c) reject all incoming product. The registration tolerance can be also specified from centerline of hole to the centerline of the land pattern. This is the most straight forward way and the most easily measured and understood by the designers, fabricators and quality personnel.

TABLE 3 - HOLE CENTERLINE TOLERANCES

FEATURE	CLASS 1	CLASS 2	CLASS 3	CLASS 4	CLASS 5
Greatest dimension from datum less than 6.000					
DIAMETRIC TOLERANCE*	0.020 (0,51)	0.014 (0,36)	0.010 (0,25)	0.006 (0,15)	0.004 (0,10)
COORDINATE TOLERANCE	±.007 (0,18)	±.005 (0,13)	±.003 (0,08)	±.002 (0,05)	±.0015 (0,04)
Greatest dimension from datum over 6.000					
DIAMETRIC TOLERANCE*	0.028 (0,71)	0.020 (0,51)	0.014 (0,36)	0.010 (0,25)	0.007 (0,18)
COORDINATE TOLERANCE	±.010 (0,25)	±.007 (0,18)	±.005 (0,13)	±.003 (0,08)	±.0025 (0,06)

*The stated tolerance is the permissible diametric movement of the true center of the feature in a circular area around the true position point regardless of feature size.

One of the first considerations the designer must make is what registration tolerance can be allowed to keep the holes within the conductor pattern regardless of spacing and hole size requirements. Or what amount of breakout can be tolerated where the land size, because of electrical requirements, must be smaller than needed. If the requirement dictates there should be a minimum of .002 copper around each hole then he must determine the centerline to centerline tolerance required to maintain this annular ring, the minimum amount of copper (metal) around the hole on the narrow side, with a specified land diameter.

In IPC D300, there is a paragraph that deals with this consideration. This paragraph allows the designer to determine the size of land required where the hole size and positional tolerances are known.

9. LAND (TERMINAL AREA) SIZE.

- 9.1 **DESIGN FEATURE.** The total accumulation of tolerances must be considered in selecting terminal size in relation to hole size. Since only one unknown is permissible, you must select either the hole maximum diameter or the terminal area size, and the class tolerance needed for hole position, line reduction, and terminal position.

Example: Using 0.030" (0,76) maximum diameter hole.

- A. Hole maximum diameter 0.030" (0,76). (Given)
 - B. Hole positional tolerance regardless of feature size. Table 3, Class 4.
 - C. Terminal area positional tolerance. Table 4, Class 4.
 - D. Total possible reduction on the diameter due to processing. Table 6, Class 4.
- Note: Terminal area will be reduced in diameter just as conductors are reduced.
- E. Minimum edge of hole to edge of terminal area, i.e., annular ring. (As specified.)

$$\begin{aligned}
 \text{Minimum Terminal Area Diameter} &= 2 \left(\frac{A}{2} + \frac{B}{2} + \frac{C}{2} + \frac{D}{2} + \frac{E}{2} \right) \\
 \text{(example)} &= 2 \left(\frac{0.030}{2} + \frac{0.006}{2} + \frac{0.014}{2} + \frac{0.002}{2} + .002 \right) \\
 &= 2 (0.015 + 0.003 + 0.007 + 0.001 + 0.002) \\
 &= 0.056 \text{ inch}
 \end{aligned}$$

$$\begin{aligned}
 \text{Minimum Terminal Area Diameter} &= 2 \left(\frac{0.76}{2} + \frac{0.15}{2} + \frac{0.36}{2} + \frac{0.05}{2} + \frac{0.05}{2} \right) \\
 \text{Metric (example)} &= 2 (0.38 + 0.075 + 0.18 + 0.025 + 0.05) \\
 &= 1.42 \text{ mm}
 \end{aligned}$$

Many times, a designer, through necessity, will have to design a board with various size pads and even then many pads may have to be cut or flattened. In this case, he may want to specify a Class 1 registration tolerance to take advantage of a low piece part price and knowing breakout will occur will probably want to limit the expected breakout to the workmanship standard IPC D320

TABLE 6 - MINIMUM ANNULAR RINGS.

Land minimum annular rings shall be in accordance with Table 6. [NOTE: When land diameters are reduced by trimming, the master drawing shall stipulate where minimum annular ring shall be measured.]

TABLE 6. - MINIMUM ANNULAR RINGS.

	CLASS 1	CLASS 2	CLASS 3	CLASS 4	CLASS 5
UNSUPPORTED	75% Enclosed	90% Enclosed	No Breakout	0.010 (0,25)	0.015 (0,38)
SUPPORTED	75% Enclosed	90% Enclosed	Tangent	0.003 (0,08)	0.005 (0,13)

Workmanship standards probably have the most variation of interpretation between the board fabricator, designer and/or product engineer and quality control.

IPC D320 has tried to classify various visual attributes such as: cracks, chips and fibers (Table 3):

TABLE 3. - CRACKS, CHIPS & FIBERS FROM INSIDE EDGE (Maximum)

FEATURE	CLASS 1	CLASS 2	CLASS 3	CLASS 4	CLASS 5
Cracks & Chips	0.040 (1,02)	0.020 (0,51)	0.010 (0,25)	0.005 (0,13)	0.005 (0,13)
Fibers	0.030 (0,76)	0.020 (0,51)	0.010 (0,25)	0.005 (0,13)	0.005 (0,13)

And visual inspection in the conductor pattern (Table 5):

TABLE 5. - ALLOWABLE VISUAL IMPERFECTIONS IN THE CONDUCTOR PATTERN (Maximum)

ATTRIBUTES	CLASS 1	CLASS 2	CLASS 3	CLASS 4	CLASS 5
Conductor Width- Nicks & Pinholes	50%	35%	25%	20%	15%
Conductor definition*	0.010 (0,25)	0.010 (0,25)	0.005 (0,13)	0.005 (0,13)	0.003 (0,08)
Roughness, (Crest to Trough)	0.015 (0,38)	0.010 (0,25)	0.005 (0,13)	0.005 (0,13)	0.005 (0,13)
Scratches (Depth)	50%	35%	25%	20%	15%

*As measured to the production master.

It should be understood the more stringent the visual attributes, the more sophisticated the tooling must be. Sometimes it becomes a sorting problem. The only recourse the fabricator can have in this case is to manufacture enough product to cover the scrap. It is possible that very close tolerances are necessary and the board fabricator will then use the proper tooling and safe guards to produce the type of product specified, and he will make sure the price will insure his making a profit. These boards can be very expensive.

Remember unnecessarily tight tolerances can increase the cost of the piece part, sometimes as much as 10 times the expected cost. Do not be fooled by the company that bids low because the close tolerance is hidden or overlooked. This company will often request waivers, an increase in price or at best, will increase the price on the next order.

In some cases, tooling will be made only to find it is impossible to manufacture to the expected tolerance. It is better to understand the capabilities of the material, process and tooling before committing the order. Clear and easily understood drawings and specifications are necessary to allow a reasonable and fair quotation. If possible, a meeting with the printed circuit board fabricator can be very helpful.

LCS 352:60:439

MANUFACTURING SYSTEMS CONTAINING CSP AND LOT PLANS

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INTRODUCTION

A great deal of attention has been given to the problem of constructing "optimal" single or interrelated Lot-By-Lot (LBL) sampling plans. Corresponding efforts directed at the construction of "optimal" single and interrelated Continuous Sampling Plans (CSP-1) have been much more restricted. The paper develops a dynamic programming model for determining "optimal" sequences of interrelated LBL and CSP-1 plans with specifiable process averages (with associated control costs) and limits on average outgoing quality.

MODEL FORMULATION

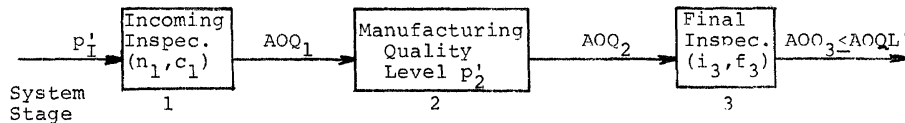


Figure 1 Single Manufacturing Stage with LBL and CSP-1 Inspection Stages

Figure 1 depicts the model of interest. The vendor's process average p_1' is assumed specifiable with an associated per unit cost of:

$$k_4(p_1') = \frac{\gamma}{p_1'} + \delta$$

where γ and δ may be estimated from the vendor's pricing information.

At stage one the vendor's material (submitted in lots of size N_1) is sampled via an LBL rectification plan whose parameters (n_1, c_1) must be determined by examining the LBL expected cost function. This cost function is comprised of the sum of the expected per unit costs of inspection K_{S1} :

$$K_{S1} = \frac{k_{21} ATI_1}{N_1}$$

$$\text{and } ATI_1 = n_1 + (N_1 - n_1) \left[1 - \sum_{x=0}^{c_1} \frac{e^{-n_1 p_1'} (n_1 p_1')^x}{x!} \right]$$

where k_{21} is the average per unit inspection cost and the expected unit repair cost K_{R1} where:

$$K_{R1} = \frac{k_{11} p_1' ATI_1}{N_1}$$

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where k_{11} is the average unit repair cost, therefore the total expected inspection station cost is:

$$TUISC_1 = \frac{ATI_1}{N_1} (k_{11} p'_1 + k_{12}).$$

The material then proceeds to be progressively manufactured at Stage two where the fabricated unit reflects either vendor or manufacturing defects with probability

$$AOQ_2 = AOQ_1 + p'_2 - p'_2 AOQ_1 = AIO_3$$

where p'_2 is the selected process average at manufacturing stage two with expected per unit cost:

$$k_3 (p'_2) = \frac{\alpha_2}{p'_2} + \beta_2$$

with α_2 and β_2 being constants associated with the fabrication process.

The fabricated units are then inspected via a CSP-1 plan at stage three with required $AOQ \leq AOQL$, the specified Average Outgoing Quality Limit. The expected per-unit costs of inspection and repair corresponding to Stage one are now:

$$K_{S3} = k_{23} AFI_3$$

$$\text{and } K_{R3} = k_{13} p'_3 AFI_3$$

$$TUISC_3 = AFI_3 (k_{13} p'_3 + k_{23})$$

Dodge (1) has demonstrated that for CSP-1

$$AFI_3 = \frac{u_3 + f_3 v_3}{u_3 + v_3}$$

$$\text{and } AOQ_3 = AOQ_2 (1 - AFI_3)$$

$$\text{where } u_3 = \frac{1 - q_3^{i_3}}{p_3 q_3^{i_3}}$$

$$v_3 = \frac{1}{f_3 p_3}$$

$$\text{and } \begin{matrix} i_3 = \text{clearance number for Stage three} \\ f_3 = \text{sampling frequency for Stage three} \end{matrix}$$

which are to be determined by the algorithm. The total expected per unit cost for the three stage system is therefore

$$TSUC = k_4 (p'_1) + TUISC_1 + k_3 (p'_2) + TUISC_3$$

where n_1, c_1, p'_2 and i_3, f_3 must be selected to minimize TSUC subject to $AOQ_3 \leq AOQL$.

DYNAMIC PROGRAMMING SOLUTION

Since the TSUC expression is the sum of four individual cost expressions it is convenient to decompose the problem via Dynamic Programming⁽²⁾. The procedure essentially solves for the decision variables, sequentially, stage by stage, in lieu of simultaneously. The additional notation required for this formulation is ⁽³⁾

$r_i =$ expected per unit cost at stage $i = 1, 2, 3$

$f_i(\text{AOQL}) =$ minimum cumulative expected system unit cost through stage i as a function of the Average Outgoing Quality Limit for Stage $i = 1, 3$ and for $i = 2$, $\text{AOQL} = \text{AOQ}$.

$Q_i =$ $r_i + f_{i-1}(\text{AOQL})$

$D_i =$ decision variables at stage i

therefore

$$f_i(\text{AOQL}) = \min_{D_i} [Q_i] = \min_{D_i} [r_i + f_{i-1}(\text{AOQL})]$$

Stage One Minimization Procedure

The solution for p'_1 , n_1 , and c_1 for a given AOQL_1 output is to establish a grid of feasible p'_{1j} values and solve at each grid point p'_{1j} for the n_1 and c_1 which minimize ATI_1 by the Dodge-Romig procedure⁽⁴⁾. The resultant expected per unit cost for each grid point p'_{1j} is:

$$r_1 = \frac{\gamma}{p'_{1j}} + \delta + \frac{\text{ATI}_1}{N_1} (k_{11} p'_{1j} + k_{12})$$

and $D_1 = p'_1, (n_1, c_1)$

This procedure is repeated for each successive grid point p'_{1j} until the value of p'_{1j} is found which minimizes the expression for the given AOQL value. The procedure is then repeated across a corresponding grid at AOQL_{1j} values with the best p'_{1j} , n_1 , c_1 being solved for each AOQL_{1j} grid value.

Stage Two Minimization Procedure

At stage two

$$Q_2 = r_2 + f_1(\text{AOQL}_{1j}') = \frac{\alpha_2}{p'_2} + \beta_2 + f_1(\text{AOQL}_{1j}')$$

and

$$D_2 = p'_2$$

We now set up a grid of AOQL_{2j} values and solve for the p'_2 value which minimizes Q_2 for each AOQL_{2j} . Note that since

$$\text{AOQL}_{2j} = p'_{3j}$$

$$p'_2 = \frac{p'_{3j} - \text{AOQL}_{1j}'}{(1 - \text{AOQL}_{1j}')} = \frac{\text{AOQL}_{2j} - \text{AOQL}_{1j}'}{(1 - \text{AOQL}_{1j}')}$$

Hence, we need only pick an AOQL_{2j} grid value, recall the first AOQL_{1j}' value which resulted from Stage One minimization, and solve directly for p'_2 . This procedure is repeated for all feasible combinations of AOQL_{2j} and AOQL_{1j}' until the minimum value of Q_2 is found for the current AOQL_{2j} value. The previous AOQL_{2j} value is changed to AOQL_{2j+1} and the procedure continues until the largest feasible AOQL_{2j} value is completed. Each combination of AOQL_{2j} and AOQL_{1j}' so found is saved.

Stage Three Minimization Procedure

At stage three

$$Q_3 = r_3 + f_2(\text{AOQL}_{2j}') = \text{AFI}_3 (k_{13} \text{AOQL}_{2j}' + k_{23}) + f_2(\text{AOQL}_{2j}')$$

and

$$D_3 = i_3, f_3$$

with specified $AOQ_3 \leq AOQL'$.

Now Resnikoff⁽⁵⁾ has shown that for

$$AOQL_2 = AIQ_3 \geq AOQL'$$

AFI_3 will be minimized when

$$i_3 = \frac{1 - AIQ_3}{AIQ_3 - AOQL'}$$

and

$$f_3 = \frac{AIQ_3 - AOQL'}{AIQ_3 - AOQL' + AOQL' (1 - AIQ_3)^Q}$$

where

$$Q = \frac{(1 - AIQ_3)}{AOQL' - AIQ_3}$$

which yield

$$AFI = \frac{AIQ_3 - AOQL'}{AIQ_3}$$

However if $AIQ_3 \leq AOQL'$,

AFI_3 can be made as close to zero as is consistent with desired protection against "spotty quality" by choice of arbitrarily small f_3 . For purpose of simple demonstration, we shall always set $f_3 = 0$ for $AIQ_3 \leq AOQL'$ which of course yields $AFI_3 = 0$.

We can proceed, therefore, by using the input grid of $AOQL_{2j}'$ values and set either $AFI_3 = 0$ if $AOQL_{2j}' \leq AOQL'$, or

$$AFI_3 = \frac{AOQL_{2j}' - AOQL'}{AOQL_{2j}'}$$

if $AOQL_{2j}' > AOQL'$ and thereby, determine the values of $AOQL_{2j}'$, i_3 , f_3 which yield the minimum combined cost for the three stage system, i.e. the minimum of Q_3 . Once these values are determined we can backtrack through stages two and one to determine their optimal values by recalling the decision variable values which lead the optimal values for $AOQL_{2j}'$ and $AOQL_{1j}'$, respectively. Finally, it is to be noted that since we have used grid search in conjunction with a complex TSUC response function, the optimal values may yield only a local instead of a global minimum.

EXAMPLE PROBLEM

Table 1 contains the specific values of the example problems parameters. Table 2 and 3 contain the solutions determined for the initial grid size of .1 and final grid size of .005, respectively. (Intermediate solution for grid sizes of .05, and .01 have not been shown because of space limitations.) Note that the required $AOQL_3'$ for the system is 10%.

Table 1. Example Problem's Parameters ($AOQL'_3 = .10$)

Stage No.	Stage Type	l_i	$2i$	α_i	β_i	γ_i	ζ_i
0	Dummy	-	-	-	-	.006	.5
1	LBL ($N_1=400$)	5	.5	-	-	-	-
2	Mfg.	-	-	1	1	-	-
3	CSP-1	50	1	-	-	-	-

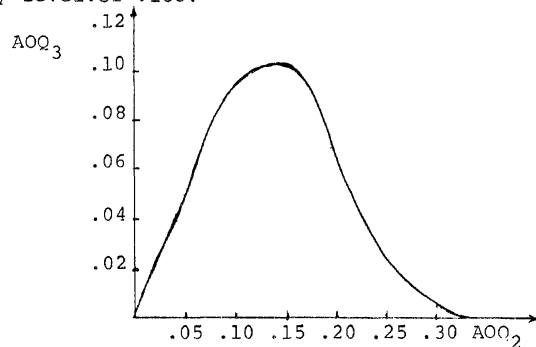
Table 2. Solution for Grid One Size = .1

Stage No.	Stage Type	Decision Variable Values	Q_1^* = Minimum Cumulative Expected Unit Cost
0	Dummy	$p_1^* = .10$	-
1	LBL	$n_1^* = 400$ $c_1^* = 0$	1.56
2	Mfg.	$p_2^* = .10$	12.56
3	CSP-1	$i_3^* = \infty$ $f_3^* = 0.0$	12.56

Table 3. Final Solution for Grid Size = .005

Stage No.	Stage Type	Decision Variable	Q_1^* = Minimum Cumulative Expected Unit Cost
0	Dummy	$p_1^* = .035$	-
1	LBL	$n_1^* = 400$ $c_1^* = 0$	1.35
2	Mfg.	$p_2^* = .135$	9.75
3	CSP-1	$i_3^* = 24$ $f_3^* = .0096$	11.76

Figure 2 contains the AOQ curve for the CSP-1 plan selected for Stage 3. It is to be noted that in accordance with the previously developed AFI formula for $AOQL_{2j}' > AOQL' = .10$ that $AFI_3 = (1.35 - .10)/.135 = .259$ and that indeed $AOQ_3 = AOQL' = .10$ at the average incoming quality level of .135.

Figure 2. AOQ Curve for Stage 3 ($i_3^* = 24$, $f_3^* = .0096$)

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LCS 221:70:000

SO YOU WANT TO DO A SUPPLIER SURVEY IN THE WORST WAY

PART II

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VENDOR-VENUE

After a successful two year run on the ASQC circuit (15 performances) the Vendor-Vendee Technical Committee is returning to center stage by popular demand with Part II of its morality play of "So You Want To Do A Supplier Survey: - In The Worst Way".

The play, presented at the 30th ATC in Toronto, has the professional survey team from Exact Products surveying the highly competent Quality Widgets. The other half of the play had Far Out Enterprises surveying Whoopee Widgets. The latter survey was both hilarious and horrendous as we watched the two teams out-do the "F Troop" without really trying. The actors portrayed some of the most common evaluation mistakes and the audience roared with laughter because most of us recognized these boners all too well.

After the show the audience suggested that roles be reversed. Let Far Out Enterprises deal with Quality Widgets and Exact Products survey Whoopee Widgets, after all, this combination probably represents true to life conditions more accurately.

That is what Part II is all about, so come and enjoy the show. See what happens to Sam, the crusty old Quality surveyor, the four martini lunch, George's and his purchasing agent kickback, and "Does Jungle Jim the Vice President ever learn what a quality survey is?"

The show should be fun and we might even learn a little on how to handle unique situations. We all need it even if we all work for Exact Products, because we are always dealing with Far Out Enterprises or Whoopee Widgets.

LCS 351:40:000

THE UNSOPHISTICATED QUALITY VENDOR

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By definition "The Unsophisticated Quality Vendor" is one, through lack of knowledge, that has not implemented an effective quality system.

The Vendor-Vendee Technical Committee, as one of its long range projects, is exploring ways and means to convert "The Unsophisticated Quality Vendor".

Come and join with us as this program is designed for you, the audience, to participate in the search for the answers and determine what are the Society's responsibilities in this endeavor.

Our guests will be:

Mr. John Song: President, Magenta Plastics. John represents the small vendor. He is unique in that he has recognized the advantages that can be gained with an effective quality system. We can all benefit from his trials and tribulations in the Quality arena.

Mr. Don McNeill: Chief, Quality Assurance Telecommunications and Electronic Branch Canadian Government. Don has had considerable overseas experience both in Europe and Australia. Don may be able to give us some insights on how the problem is approached on the other side of the oceans.

Mr. Harry D. Greiner: President Management Systems Analysis. Harry's long career as a quality manager for Budd cast him in a role of a vendor, as a Product Assurance Manager for RCA he was a vendee. In his present capacity of a management consultant he works both sides of the street. Harry's technical expertise is welcomed.

Mr. William Anderson: General Electric Re-Entry & Environmental Systems Division will act as host.

You, the audience, will be afforded the opportunity to express your opinions and ideas, challenge the guests and ask pertinent questions.

This is intended to be a working session. The ideas generated at this session will reflect in a future "How To Handbook" planned by your Vendor-Vendee Technical Committee.

LCS 351:40:000

DON'T MAKE THEM LISTEN - MAKE THEM DO

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THE PROBLEM

During the last years many Managing Directors have heard the following statement from their QC Managers:

"We must develop a more systematic approach to our quality problems. We will have to design a better system for calculating our quality costs, a written procedure for identification of accepted and rejected batches, a better way of evaluating our vendors, and so on. This is all necessary for many reasons, but first of all - our customers demand it."

Let us try to imagine what thoughts these words bring about in the mind of the Managing Director:

"This will cost at least \$ 40,000 to 50,000."

"What's wrong with the companies that we buy from? Besides, that is not his business, he is supposed to inspect the end product."

"Quality costs? We have had very few customer complaints the last 6 months."

"I don't believe that our customers really demand this. They will continue to buy from us as long as we deliver good products."

"Nobody will ever read the written procedures he is talking about. They will just end up in a dusty binder somewhere."

So the Managing Director will probably answer his QC Manager something like this:

"Yes, I agree that we should work systematically in order to maintain our good quality reputation. But at the moment we cannot allow an increase in our over-heads, so I must ask you to achieve your objectives step by step with your present resources."

ANALYSIS

Obviously there is a lack of knowledge on the part of the Director. He does not know what we mean by quality costs or vendor evaluation. He is not aware of the change in customers' interest, from inspecting the products to demanding an appropriate Quality Assurance System. He does not see, that a systematic quality control can save him money and make sure that old customers stay and new ones turn up.

Let us not put the blame on the director, at least not all of it. Nothing is ever achieved by blaming people (and definitively not by blaming your boss!). It is much more useful to try to find out what we could do about the situation.

It seems to be a very trivial question of information. A couple of hours would be enough to teach the whole top management the concept of modern Quality Assurance, and convince them that there is money to earn. And during my first years as a management consultant, this was what I was hired to do on many occasions. I had a fine information material, developed by the Swedish Association for Metalworking Industry. I had a true belief in what I was preaching. And I considered myself to be an excellent lecturer!

In the beginning I also had the feeling that I was completely successful. The managers I spoke to listened carefully, and they always told me after my presentation, that they had found it extremely interesting. So I got the impression, that I was doing a very important job, that brought the QA concept forward within Scandinavian industry.

But after some time I decided to do some follow-up on my previous assignments. I called my clients to hear what had been done as a result of my presentations. The result of this investigation was most disappointing. Very little had been achieved, in many cases nothing had been done at all. Immediately after I had left the company, everything went back to normal again.

The only explanation I have been able to find - and it is confirmed by my recent experiences - is that my information was understood only in a pure intellectual sense. And that is not enough! The managers must understand the problems with their feelings too, they must feel the problems on their bodies before they will put them higher up on their priority list.

SOLUTION

Unfortunately we cannot make the Managing Director QC Manager for a year or so, even if that of course would make him see that some of our demands are right. No, we must find a method, similar to accelerated life-length-testing, that enables us to create true involvement in a short period of time.

The following program has proven successful on several occasions, in companies of different sizes and branches.

Target group: Top Management and other key persons. At least 10, at most 20 people attending.

Time and place: Two days in a quiet environment outside the company.

Program: Principally the conference or seminar consists of three steps, namely

- the policy step
- the problem solving step, and
- the planning step.

All three steps are taken as group works or syndicates.

The policy step. The participants get a number (15 - 20) of written statements about quality, the quality situation in the company, the organization of the quality work, etc. They have to state their opinion about all the statements, and they have 5 possibilities to choose between: Agree totally, agree partly, uncertain, disagree partly and disagree totally.

When everybody has made up his mind, people go out into smaller groups, i. e. 5 - 7 persons, and now they shall try to agree on a common view on each statement. The discussion that takes place in these groups leads to a conscious evaluation, that will make a base for a policy.

The problem solving step. In this next exercise the participants are given two alternative plans of action for each of 5 - 7 important areas within the field of QA. It should be areas where some action is necessary, and where it is known to exist different opinions about what should be done. The two action plans shall be extremes in two different directions. The participants are asked to distribute 10 points between the two plans for all of the descibed areas. You can for example for one area give 10 points to plan A and 0 points to plan B, meaning that you totally agree with plan A. For another area you can, if you find the two plans equally good (or equally bad), split the points 5 - 5.

Also in this exercise you try to come up with a group solution that everyone in the group can agree upon. The result is often, that the explanations the groups give to why they have decided on a certain distribution of points, is really a third plan of action, which is a combination of the best in the two original plans. This means, that you have reached an agreement on how to solve the problems within that particular area.

The planning step. At this stage, the participants usually are rather excited about the plans of action they have agreed upon. But this is only a positive attitude. It is now necessary to evaluate and compare the benefits and the drawbacks of the

plan chosen for each area. Only when this is done you have got a true motivation to carry out the plan. If you merely have got a positive attitude, there is always a risk that your enthusiasm fades off when you realize the efforts you have to make.

So this is why the third step is so important. The groups must draw the conclusions of their plans of action, i. e. what resources they have to allocate.

CONCLUSION

The key elements of the program are:

1. You don't tell people what has to be done. You give them the problems and let them come up with the solutions, not in detail but the principals. It is in the following project work that you tackle the details with the help of your specialists. And it is a great advantage for the specialists to know, that they can always turn to the managers for guidance - they are familiar with the project.

2. The group exercises are designed in a way that makes everyone quantify his view before he gets the opportunity to listen to other people's opinion. Nobody has got a chance to be too tactical, everybody must be prepared to explain his opinion about a statement or a plan of action.

3. The participants do not only create a plan on how to tackle the problems. They also make a thorough evaluation of the needs of resources to carry out the decisions that are made.

4. The conference is held in an undisturbed environment, and the time involved is reasonably long. Do not try to achieve a result in a shorter time, or with the program divided into shorter periods. It takes some time to clear one's mind from other problems. If you switch too often you may find yourself spending most of your time getting rid of the last problem you discussed.

The companies that have used this program have found, that they did not only solve some problems, they also created a basis for future problem solving. It is a general observation, that people who have achieved something together get along fine in the future. It is a true asset to an organization to have links of this informal kind, built on personal appreciation and trust.

LCS 670:10:000

GENERIC QUALITY STANDARDS - A CANADIAN APPROACH

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INTRODUCTION

During the past few years, activities in industry, standards organizations, legislatures, etc., made it clearly evident that a co-ordinated effort was required with respect to the Quality field in both the product and service industries. The proliferation of quality documents, in an unco-ordinated way, was leading to a potentially chaotic situation. This was particularly critical to the small supplier serving a variety of industrial fields.

The Canadian Standards Association (CSA) recognized this problem and initiated a Steering Committee on the Assurance Sciences to review the needs, in this field, for voluntary consensus standards. The term Assurance Sciences was used in lieu of Quality Control or Quality Assurance in an endeavour to improve the communications between the various disciplines involved.

The Standards Council of Canada accredits the Standards Writing Organizations (SWO's). Through the Council, agreements are reached on which SWO will prepare consensus standards in their particular area of expertise. In the Quality field, CSA has now been recognized as the SWO responsible for the preparation of an integrated system of Assurance Standards for promulgation as National Standards of Canada.

In developing this integrated system, it is important to ensure that the 'needs' of the other accredited Canadian SWO's are known. It is also important to harmonize these activities with the various international activities in this field.

ORGANIZATION

In order to meet the overall requirements, CSA has initiated the Steering Committee on Assurance Sciences to guide and co-ordinate the activities of the various technical committees and other committees involved in the development and application of a system of Assurance Standards.

Steering Committee members are selected for their individual expertise. However, in order to maintain a balanced approach, every endeavour is made to balance members between the three categories:

1. Supplier organizations.
2. User organizations.
3. Regulatory bodies and general interest, including academic.

In most cases the members representing the supplier and user organizations will be filling a dual role since most suppliers are also major users of material and/or services, and most of the user organizations are suppliers of services.

The activities of the Steering Committee are supported by:

1. Secretariat, provided by CSA.

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2. Executive Committee.
3. Co-ordinating Committee.
4. Consultative Committee.

The CO-ORDINATING COMMITTEE has been formed as a staff aid to the Steering Committee. The membership of this committee will comprise the representatives of the accredited Canadian SWO's, certain of the Government Procurement Agencies, and other selected bodies. Representatives of the CO-ORDINATING COMMITTEE are expected to reflect the 'needs' of their respective agency or body to the Steering Committee. They are also expected to provide visibility to their respective body on the activities of the Steering Committee. In this way, we hope to ensure a co-ordinated approach which will meet the needs of all organizations wishing to use the ultimate standards.

The CONSULTATIVE COMMITTEE is a small committee of experts in the Assurance fields who can act as consultants and advisors, assist with interpretations, and provide other related guidance, on request, to product or service technical committees of CSA and the other SWO's.

OBJECTIVE

THE PRIMARY OBJECTIVE OF THE STEERING COMMITTEE ON ASSURANCE SCIENCES IS TO DEVELOP AN INTEGRATED SYSTEM OF STANDARDS TO PROVIDE REASONABLE ASSURANCE THAT PRODUCTS AND SERVICES MEET THEIR INTENDED REQUIREMENTS. IT IS THE INTENT THAT THESE STANDARDS CAN BECOME NATIONAL STANDARDS OF CANADA.

INTEGRATED SYSTEM

It has been agreed that the integrated system will basically comprise four types of documents:

1. Generic System Standards.
2. A Management (Administrative) Guide.
3. Technological Standards.
4. Product or Service Standards.

The Steering Committee on Assurance Sciences is responsible for the development of the first three categories of these standards. The fourth category - Product or Service Standards - falls under the jurisdiction of the Steering Committee responsible for a particular product or service in CSA's case, or under the jurisdiction of the appropriate SWO in other cases.

ASSURANCE SYSTEM STANDARDS

It has been recognized that modern industrial management, normally, determines and measures the effectiveness of its organization by means of quantitative objectives. Successful industrial management is a creative process, which can result in a variety of solutions to common objectives. Each solution must match the resources available within a particular situation to the objectives.

One of the key objectives for all organizations is the need to assure the integrity of the product or service provided. In some areas, this objective has arisen through the requirements of specific contracts. In general, however, this demand has arisen through industrial conscience and competition, plus consumer awareness.

Recognizing the above, it is the intent to develop the System Standards in terms of objectives. By defining the assurance requirements in this way, industrial management will be able to apply their resources in the most efficient manner applicable to their product or service. It must be recognized that System Standards can have a dual purpose. Firstly, they can provide reasonable assurance, to management, and certifying agencies, that products or services meet their intended requirements. Secondly, they can form part of the contractual requirements for a particular product or service. The complexities of system required for each of these purposes need not be the same.

Therefore, it has been decided that standards will be issued covering the different levels of system complexity. These comprise:

1. Quality Assurance Standard - a Quality system standard applicable to an organization having responsibility for a product or service from its conception to its application, including installation and dismantling where applicable.
2. Quality Control Standard - a Quality system applicable to organizations providing complex or critical material or services to the customer's conception and design documentation.
3. Inspection System - a Quality program applicable to organizations providing repetitive and/or simple material or services.

These standards, defining 'what' the requirements are for each level of complexity, can readily be used as the basis of measuring the effectiveness of the Quality program. It can form the basis of certifying the Quality program of an organization to a known level for a particular product line. The technologies and methodology used will depend upon the complexity of the product line. The basic requirements of the standards, however, will be based upon those elements of the Quality Assurance profession which are common to all product lines.

MANAGEMENT GUIDE

A Management Guide is in the process of preparation, taking the form of a generic 'Guide to the Interpretation and Application of Quality Assurance Standards'.

This document is intended to provide visibility to the Chief Executive Officer (CEO) and other senior members of management, outside the Quality profession, on 'why' the various requirements exist within the system standards. The Guide will be based on the Quality Assurance system, since any of the lower levels of system complexity will comprise selected elements of the Quality Assurance system. The program covered by the guide will cover the total life cycle of the product or service. The combination of the Guide and the applicable system standard should provide the CEO with the answers to the 'what' and 'why' of an Assurance system. This will permit him to exercise his management prerogative in assigning responsibilities for the implementation of various aspects. It will also provide him with information on which to measure the effectiveness of the management of his Quality program.

TECHNOLOGICAL STANDARDS

Technological Standards are required in each of the major elements of Quality expertise. Each standard will cover a particular area of expertise or technological requirement of the system standard.

These standards will provide the 'how' to implement the various requirements of the system standard. It will be essential that we ensure that these standards do not inhibit management creativity in matching the resources available to the product and/or service need.

PRODUCT/SERVICE STANDARDS

Product or Service Standards will be prepared by specialist groups, product or service, as required. These standards may incorporate or reference the use of the management and technological standards as necessary to suit the peculiarities of the particular product, service or application.

PLANNING

One of the supporting requirements we set ourselves was to not add to the proliferation of Assurance standards where an existing standard had been demonstrated as meeting the requirements of the Steering Committee. This implied a fairly comprehensive review of the existing generic standards as part of the planning operation.

The initial step in the planning of the Steering Committee activities was to develop a Function Tree covering the various elements of an Assurance system.

The Function Tree is a well known system analysis tool. The prime function is sub-divided into its various supporting functions. Each supporting function in turn is sub-divided into lower level supporting functions. By repeating this process until the basic Quality elements are identified for each function, it is possible to develop a system diagram providing full visibility on the various elements of the system.

Having developed the Function Tree for the Assurance system, indexes for various standards issuing organizations, e.g. Canadian Standards Association, Canadian Government Standards Board, Department of National Defence, Department of Defense, American National Standards Institute, British Standards Institute, etc., were examined to identify those generic standards already in existence for the various elements.

As the system of standards develops, revisions will undoubtedly be required to the initial Function Tree. The Function Tree will, however, still provide a ready reference to ensure co-ordination of the activities of the various technical committees.

PREPARATION OF STANDARDS

It has been recognized that the writing of standards by large committees is fraught with the same hazards that apply to designing a product by a large committee. Therefore, we have instituted a series of small Task Forces to carry out the preparation of the initial drafts. In certain cases these Task Forces report to technical committees, and others to the Steering Committee.

When the first drafts have been developed, technical committees and technical sub-committees will be initiated to review the drafts and to act as guides to the further development by the Task Forces of the particular standards.

It has been stressed to each of the Task Forces that it is not the intention of the Steering Committee to develop new standards where existing standards suffice. If an existing standard meets the needs in its existing form, or with minor modifications, steps are being taken to implement some form of Canadian Notice of Adoption which will indicate the identification and revision of the document adopted, and its degree of acceptability including any minor deletions and/or additions. This notice of adoption will be subject to periodic review. If the referenced document is changed by the originating body, the revised document will be subject to review with respect to its adoption into the Canadian system.

STATUS

Currently, technical committees are active in the following areas:

1. Guide to the interpretation and application of Quality Assurance systems.
2. Application of statistical methods.

The Technical Committee on the Management Guide has reviewed the second draft of the Guide. The third draft is currently in the process of preparation.

The Technical Committee on Statistical Methods has a number of sub-committees reviewing the various statistical fields to determine the extent of its activities. This Technical Committee has been closely harmonized with the Canadian National Committee for ISO/TC69. Both Technical Committees have the same Chairman, plus a number of common members.

In addition to these Technical Committees, Task Forces have been initiated to review the requirements in the following areas:

1. Assurance Systems.
2. Design Integrity (Assurance).
3. Production Assurance.
4. Metrology.
5. Software Assurance.
6. Quality Audit.

The status of the work within each of these Task Forces tends to vary. However, each is charged with the responsibility for:

1. Reviewing the existing standards.
2. Assessing the need for new or modified standards.
3. Making recommendations with respect to standards.
4. Making recommendations with respect to the Technical Committee membership.
5. Preparing a Statement of Work for the Technical Committee.

Each of these Task Forces will be utilizing segments of the Function Tree to indicate their requirements for standards.

As standards are prepared or notices of adoption are prepared, they will firstly require balloted approval by the Technical Committee. The approved documents are then subject to review and approval by the Steering Committee on Assurance Sciences who in turn are responsible for submitting these documents to the Standards Policy Board for submission to the Standards Council of Canada.

HARMONIZATION

The broad spectrum of membership within the Technical Committees should ensure the harmonization of the various needs. A similar breadth of industrial and service expertise in the Steering Committee on Assurance Sciences, supported by the Co-ordinating Committee, should ensure that the various standards developed harmonize into a national integrated system.

It is essential that the Canadian system of Assurance standards is harmonized with the International systems - ISO, IEC, etc. Currently, our harmonization is concentrating on three organizations - ISO, IEC, and CEE. In these areas, representatives of the Canadian National Technical Committees are members of the CSA Technical Committees. In at least one instance the same individual is the Chairman of both Committees. Currently, ISO/TC69, IEC/TC56 and IEC 'Q' are involved.

As an aid to international harmonization between the English language standards, formal liaison contact has been initiated between the Staff Secretariate of ANSI, BSI, and CSA as well as direct contact between the Chairmen of the corresponding Steering Committees. It is hoped that this type of liaison will serve to at least reduce the proliferation of standards in the English language.

CERTIFICATION

Whilst not forming part of the terms of reference of the Steering Committee on Assurance Sciences, it has been recognized that some form

of certification of organizations to appropriate systems standards is required, both on a national and international basis. Steps have been initiated to implement this type of activity at the National level. It is hoped that international industrial and commercial reciprocal arrangements similar to that used by NATO, can be developed for commercial and industrial applications.

CONCLUSIONS

We believe that with our approach to the development of an integrated system of National Standards, we can provide an integrated generic system meeting the 'needs' of Canadian industry, which will harmonize with the international standards.

UNIDO STANDARDS AID--THE NIGERIA EXPERIENCE

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UNIDO AID

Since its establishment in 1967, the United Nations Development Organization (UNIDO) has engaged in a continuing and increasing program of technical assistance to developing countries. Among many areas of assistance, the development of national standards organizations and related infrastructures and activities for implementing standards through programs of certification, metrology, and quality control have been of great importance to many countries. And as more countries undertake programs of industrialization, these subjects take on even greater interest in the future. Furthermore, UNIDO has collaborated with the International Standards Organization (ISO) in identifying the importance of standardization and related disciplines in the transfer of technology^{(1),(2)}, including the adoption and/or adaptation of international and other national standards in programs of transfer of appropriate technology.

Over the past several years UNIDO has provided the assistance of experts in standardization and related disciplines to no less than thirty countries. In most instances, these experts form the advisory component of UNIDO projects with the respective countries. These projects often include additional assistance such as buildings, equipment, and international training fellowships for local staff. Some projects run as little as three to six months. Others provide continuing assistance well into phases of refinement of the national program. An example of the latter is the program of UNIDO technical assistance to the Thai Industrial Standards Institute, which is now in its eighth year and with which the author was associated in its early development.^{(3),(4)}

THE UNIDO/NSO PROJECT

The UNIDO project with the Nigerian Standards Organization (NSO) of the Federal Ministry of Industries, Nigeria, was approved on October 17, 1975. The project has a long range objective "to promote the industrial and economic development of Nigeria through the development of standardization, quality control, industrial metrology, and metrication activities and their application in the industrial and business operations carried out in the country. It is expected that this would contribute towards raising the quality of industrial goods manufactured in the country, facilitating trade between Nigeria and its trading partners and bringing about an added value to Nigerian products sold abroad, thereby raising the nation's GNP".

Specific objectives resulting in major activities under the project include,

1. Strengthening of NSO management and organization.
2. Development of suitable buildings and facilities for an NSO central testing laboratory.
3. Establishment of central and subsidiary laboratories for testing, quality control (certification), metrology and calibration.
4. Strengthening of NSO's quality inspection programme and quality certification marking scheme.
5. Training of NSO Staff.
6. Training of industrial personnel.

Advisers and consultants provided by the project are to include the following,

1. Industrial quality inspection (certification).
2. Industrial metrology.

3. Chemical Analysis.
4. Materials testing.
5. Programming and construction of buildings and facilities for quality control and testing centres.
6. Laboratory testing-management, operation and selection of laboratory equipment.
7. Development and conduct of training-consulting workshops on quality control principles and techniques including quality assurance programmes and certification marking schemes.

The project became operational with the author's assignment as team leader and adviser on industrial quality inspection (certification) in January, 1977 for the 1977 calendar year. During the year an additional consultant on programming and construction of buildings and facilities completed an initial effort in the development of a permanent office and laboratory facility for NSO. Additional project activities are programmed through 1981 for implementation.

NIGERIA

Nigeria is located on the west coast of the African Continent. It has a land area of approximately 913,000 square kilometers. It is endowed with vast national, mineral and human resources, including oil and a population of over 90 million. Thus, it has one of the greatest potentials to develop an economy, culture, and industry resulting in a high quality of living for its citizens.

Nigeria is intensifying its efforts for a rapid industrial and economic development of the country. The Third Five-Year Development Plan (1975-1980) outlines the development strategy in the various sectors of the economy including emphasis accorded to the development of the industrial sector. This includes promotion of local industries for the production of commodities and services required both for the local market as well as for export purposes. An additional strategy is the decentralization of industries and related support services. This is being effected through the increasing involvement of state governments in planning industrial activities within their respective states as well as the location of Federal Government financed industrial projects at suitable rural areas. Nigeria's financial capacity has been increased considerably by the current world economic situation, especially with respect to the oil industry. This has, in turn, given rise to a burst of intensive industrial activities particularly in the construction sector and related areas.

In view of the above, it has become necessary to set up and/or strengthen the institutional and technical services infrastructure in the country. One of these is the Nigerian Standards Organization.

THE NIGERIAN STANDARDS ORGANIZATION

NSO was officially established by the Nigerian Standards Organization Decree 1971, Decree No 56, which was promulgated in December, 1971 with a commencement date of 1 January, 1970 when the Organization actually started to function. The decree lists the principal functions of the Organization as follows,(5)

- "1. to organize tests and do everything necessary to ensure compliance with standards designated and approved by the Council,
2. to undertake investigations as necessary into the quality of facilities, materials and products in Nigeria, and establish a quality assurance system including certification of factories, products and laboratories,
3. to ensure reference standards for calibration and verification of measuring instruments,
4. to compile an inventory of products requiring standardization,
5. to compile Nigerian standards specifications,
6. to foster interest in the recommendation and maintenance of acceptable standards by industry and the general public,
7. to develop methods for testing of materials, supplies and equipment including items purchased for use of departments of the Gov-

- ernment of the Federation or a State and private establishments,
8. to register and regulate standards marks and specifications,
9. to undertake preparation and distribution of standards samples,
10. to establish and maintain such number of laboratories or other institutions as may be necessary for the performance of its functions under this Decree,
11. to compile and publish general scientific or other data,
12. to advise departments of the Government of the Federation or a State on specific problems relative to standard specifications,
13. to sponsor such national and international conferences as it may consider appropriate,
14. to coordinate all activities relative to its function throughout Nigeria and to cooperate with corresponding national or international organizations in such fields of activity as it considers necessary with a view to securing uniformity in standards specifications, and
15. to undertake any other activity likely to assist in the performance of the functions imposed on it under this Decree."

For carrying out these functions, NSO at present has a staff of thirty-five professional personnel including a Director and an additional support staff of approximately fifty. This is presently below authorization levels and will need to be increased by additional recruiting. The Decree also established a governing body of the Organization known as the Nigerian Standards Council. The Council consists of some fourteen members representing a broad spectrum of government, industrial, and other organizations, such as Agriculture, Transport, Health, Works, Mines and Power, Industry, Science and Technology, and Universities, a consumers' council, and private industrial firms. The principal functions of the Council under the Decree are,

- "1. to advise the Federal Military Government generally on the national policy on standards, standards specifications, quality control and metrology,
2. to designate, establish and approve standards in respect of metrology, materials, commodities, structures and processes for the certification of products in commerce and industry throughout Nigeria,
3. to provide the necessary measures for quality control of raw materials and products in conformity with the standard specifications,
4. to determine the overall policy of the Organization, in particular with regard to the financial, operational and administrative programmes of the Organization and to ensure the implementation of the said policy, and
5. to carry out other functions imposed on it under this Decree or any other written law."

To date, NSO has published just over 80 national standards and codes of practice. More than that number of additional standards are now in various stages of committee work, approval and publication. They cover a broad range of consumer and industrial products as well as test methods in textiles, soaps, safety matches, candles, batteries, plastic bowls and buckets, milk, ball point pens, enamelware, white bread, glass bottles, cement, building blocks and bricks, steel wire and reinforcing bars, fans, crash helmets, auto and bicycle tires, electric bulbs, electric fuses, paper, gas cylinders and other subjects of economic importance.

The Organization has patterned itself on the principle of consensus of industrial, commercial and consumer opinion adopted by most standards organizations. The standards are drawn up by committees of specialists, the members of which are drawn from manufacturers, major users, government departments, universities, and any other organization with a close professional and business interest in a particular product. NSO itself provides the secretariat for these committees and is staffed with qualified men and women who prepare drafts, initiate any research work needed, survey factories, evaluate tests, and generally service the committee operations. Approvals for standards promulgation are through the Nigerian Standards Council and the Federal Ministry of Industries (FMIND).

Internationally, NSO is a full member of ISO representing Nigeria with that international body and provides documentary information in Nigeria on all ISO member bodies including foreign national standards and international standards. It is also the subscriber member of the International Electrotechnical Commission (IEC) and is Nigeria's contact point for the Codex Alimentarius Commission, the United Nations Joint FAO/WHO Food Standards Programmes.

Regionally, NSO is a founding member of the African Regional Standards Organization (ARSO). NSO was also elected to the first three year term of presidency of ARSO at the founding conference, January 10-17, 1977.

Implementation of standards was generally on a voluntary basis until 1976 when an amendment, Nigerian Standards Organization (Amendment) Decree 1976, Decree No. 20, further empowered the Commissioner (FMIND) to declare, by order published in the Government Gazette, any standard established under the principal Decree to be a Mandatory Industrial Standard, making it an offence for any manufacturer (and importer) to fail to comply with any of the requirements of such a standard. The Commissioner used the occasion of the opening of the NSO/UNIDO Training-Consulting Workshop on Quality Control Principles and Techniques, University of Lagos, on 5th September 1977 to announce mandatory standards on milk and cement.

The NSO Decree (Section 10) authorizes the Nigerian Standards Council to permit the manufacturer of a product which has been found to conform to a relevant Nigerian Industrial Standard to affix the NIS Certification Mark to a conspicuous part of its products or packaging. This program was first implemented by issuance of license to use the NIS Mark on toilet and laundry soaps to a major manufacturer on 14 October 1974 (World Standards Day). On the occasion of the following year's World Standards Day, 14 October 1975, licenses to use the NIS Mark were issued to seven additional companies, representing textiles, candles, enamelware safety matches and plastic products. Other companies are under study for licenses to use the Mark, but no additional licenses have been issued to date. This activity is expected to be enhanced considerably by the establishment of a functional department on Certification and Quality Control (C & QC) in October, 1977.

CERTIFICATION AND QUALITY CONTROL

NSO's certification program is expected to grow rapidly and serve a vital link in the implementation of standards, including raising of quality of locally produced and imported commodities and products. The first phase of the UNIDO project with NSO served to identify and provide training in areas of further development needed to strengthen the certification program. The establishment of a functional department is a significant initial step. Other steps envisaged for the program and certification group are (6),

1. Staffing and manpower planning for the C & QC department. It is expected that some personnel may continue as secretaries to a limited number of technical committees in the preparation of standards with gradual relinquishing of those duties. Additionally, the certification group will continue to call upon specific expertise from other NSO staff (e.g. textile technology, electrical technology, etc.) for its work with certain companies when such expertise is not present among those assigned to the group.
2. Organization of the information and working files associated with the present eight licensees. Updating of the factory visits, tests, etc. associated with these licensees. Uniform programs of product marking, promotion and advertisement of the NIS Mark for consumer education and encouragement of other manufacturers.
3. Development of rules and regulations pertaining to the operation, implementation and maintenance of the certification program with neat, attractive and accurate brochures for distribution to potential licensees. Some specific items include:
 - a. A General-Certification Mark Licensing Procedure,
 - b. Regulation pertaining to application and issuance of license to use the quality mark including the official application

- form, and the official license form for voluntary and mandatory --domestic and import certification,
- c. Regulation giving specifications of the standard mark,
 - d. Regulations giving rate of fees, etc.
4. Development of Schemes for Surveillance Inspection and Testing (as given in Appendix A of reference 3).
 5. Planning the expansion of the certification program. Some of the directions envisaged are,
 - a. A listing and survey of companies producing products for which there is a Nigerian standard. Follow-up mailings and visits to advise, assist and encourage these companies,
 - b. Implementation of mandatory standards by the certification program,
 - c. Consideration of certification to other than national standards,
 - d. Location and accreditation of testing laboratories,
 - e. Development of an export inspection program.
 6. Continued activation of the technical committee on Quality and Reliability including,
 - a. Establishment of a National Association of Quality Control,
 - b. Preparation of standards on quality control principles and techniques such as sampling tables, control charts, quality assurance programs, etc.
 7. Establishment of a technical (working) committee on testing and calibration to plan tests and coordinate testing facilities and programs in support of the certification program.
 8. Pursuing of international training opportunities for C & QC staff via UNIDO fellowships or other programs.
 9. Continued coordination of the Training-Consulting Workshops on Quality Control Principles and Techniques for industrial personnel.

CERTIFICATION AND MANDATORY STANDARDS

With the issuance in 1976 of Decree 20, NSO (Amendment), NSO is empowered to enforce mandatory standards. It has been recommended that this activity be accomplished via mandatory certification on these standards (5b. above). Some additional remarks pertinent to this matter follow.

Whatever the means of enforcing, to be effective, mandatory standards require adequate staffing and a program of surveillance inspection. Sometimes, the tendency to declare standards as mandatory becomes very strong in the thinking that this is the only sure way to make progress in standardization. Often the opposite effect is achieved. Especially if the surveillance and enforcement cannot keep up with the declaration of mandatory standards. Planning for the certification group must be coordinated with the effort to establish mandatory standards. One solution of the above problem may lie in a better understanding of various forms of compulsion. There are at least two levels of compulsion which may be created.

One is referred to as a "subtle compulsion", obtained by the politico-technical activity of convincing responsible authorities to specify or require quality in products and services. Large Government and commercial organizations, purchasing supplies and services from local businesses, can create a compulsion by setting required levels of quality via quality requirements in purchase contracts, building specifications, etc. and by giving preference to those businesses having certified products under the voluntary program, or even requiring such certification. This has the feature of providing an option to a local producer--he can opt to direct the manufacture of his product toward this business or he can decide not to compete in that arena and seek other markets. More promotion of this type of compulsion may accomplish equal benefits and be easier to manage.

The second form of compulsion is referred to as "hard core compulsion" obtained by the politico-technical-legal activity of decreeing by law that imported and/or manufactured products must conform to a given standard -- with associated liabilities. Mandatory standards with re-

lated certification is of this type and has its place in the overall program of industrial development. Some quality requirements need enforcement from an organization or program with a broader perspective than the manufacturer himself or his immediate customer. For example, the higher cost of electricity or even the cost of a related fire from poor quality electrical cable is most often not borne by the manufacturer of the cable or by the construction contractor -- without some independent enforcement of such quality, they may be tempted to cut their individual costs by supplying a low grade cable.

Generally, products involving personal injury or economic loss are subject to mandatory standardization and certification. The declaration of mandatory standards should be used as sparingly as possible, and then within the capability of implementation.

The procedures by which mandatory standards are declared should be examined in Nigeria. Consideration should be given to a formal program of

- (1) a public announcement of intent to establish a mandatory standard.
- (2) an appeal procedure and time interval to receive and hear comments from those affected, perhaps including a public hearing,
- (3) public notification of final decision with a prescribed grace period for start of enforcement.

TRAINING PROGRAMS

Under the UNIDO/NSO project, at least four types of training programs are considered and have begun. These are,

1. UNIDO Sponsored International Training Fellowships for NSO staff. And these are of two types, (a) group training programs on general subjects of standardization, quality control and related topics and (b) individually tailored programs on specific subjects of interest and need to the Organization. Programs of the first type include courses in Japan, India, Australia, Sweden, U.K., USSR and other countries on a rotating regional basis. NSO staff has participated in all of these. Programs of the second type take place mainly under the project and require individual coordination. Several are under development.
2. In-country Training Programs for NSO Staff. These programs are generally conducted by UNIDO Advisers assigned to the project. An extensive program was carried out by the author during the first half of 1977 on topics of Quality Control Principles and Techniques, Standardization and Certification. Other programs on Metrology, Laboratory Testing, Chemical Analysis, etc. are envisaged.
3. Seminars, Conferences, and Short Term Workshops for NSO Staff and Other Organization Personnel. These programs are organized through various associations and organizations to disseminate information and promote programs of potential benefit. Related programs during 1977 were,
 - a. Seminar on, "Evolutionary Operation: A Method for Improving the Performance of Existing Industrial Processes." to the National Chemical Engineering Society, Engineering Lecture Theatre, University of Lagos, March 26, 1977.
 - b. One-Day Workshop for Quality Control Managers of the Technical Committee on Quality and Reliability on "Quality Control Techniques, Quality Systems, National Associations for Quality Control and National Standards on Quality Methodology", NSO Conference Room, April 22, 1977.
 - c. Seminar on "Development of National Standardization and Certification in Thailand and its Implications for Nigeria", Conference Room, Federal Institute of Industrial Research (FIIR), Oshodi (Lagos), May 13, 1977.
 - d. Four-Day Workshop by UNIDO and FIIR for industrial personnel on "Quality Control in the Textile and Allied Industries", Conference Room, FIIR, Oshodi (Lagos), June 20-23, 1977.

- Conducted by two UNIDO Advisers, FIIR staff and speaker from Kaduna Polytechnic University.
4. Training-Consulting Workshops on Quality Control Principles and Techniques for Cost Reduction, Process and Product Improvement and Control for industrial personnel with NSO staff observing and assisting. These programs were conducted using the "sandwich" principle of several days of introduction lectures in a classroom/conference setting, a period of in-factory consultation during which each participant returned to his own factory to work on a problem and/or application with consulting visits by the workshop leader accompanied by NSO staff, and concluding lectures and discussions back in the conference room to summarize findings, explore additional techniques and promote future applications. Three workshops were conducted as follows,
- a. Lagos Area, University of Lagos Continuing Education Centre, September 5-23, 1977. Thirty-seven participants representing twenty-seven companies attended this workshop. Products represented include, pharmaceuticals, cosmetics, beverages, foods, confectionery, doors, electrical fixtures, enamelware, paperboard, air conditioners, wire, truck assembly, venetian blinds, paints, metal cans, etc. The workshop was opened by the Federal Commissioner for Industries drawing national attention to the program. The Manufacturers Association of Nigeria (MAN) assisted NSO in the circulation of the workshop announcement. Consultations in every factory highlighted areas of applications for quality control techniques and quality systems principles and several significant cost reduction efforts were realized within the workshop period.
 - b. Kano Area, Auditorium, College of Preliminary Studies and Conference Room of the Industrial Training Fund, Kano, October 17-28, 1977. Seventeen participants representing fourteen companies attended this workshop in addition to seven staff members of NSO. Products represented include, printing, shoes, textiles, cosmetics, pharmaceuticals, bicycles, steel construction, furniture, baked goods, cartons, etc. The Kano workshop was opened by the Kano State Commissioner for Industry, Trade and Cooperatives and also uncovered quality control applications and significant waste and cost reductions.
 - c. Kaduna Area, Murtala Mohammed Square Conference Centre, Kaduna, November 7-18, 1977. Twenty-nine participants representing ten companies attended. Products included, textiles, defence products, printing, newspaper, yeast and alcohol, sugar, live-stock feed, auto assembly, etc. As with the others, significant applications were uncovered.

These series of workshops are the beginning of a vital program of Technical assistance to industry by NSO and are seen to accomplish the following six benefits,

- a. provide direct training for the participating industrial personnel,
- b. expose participating NSO staff to more industries and consulting-investigating experience,
- c. provide much needed publicity for NSO in industry as well as in its own government organizations,
- d. provide a mechanism for encouraging industry cooperation with NSO's certification program,
- e. provide direct process and product improvement applications within participating industries, and
- f. initiate the quality improvement spiral of better products at lower costs and prompt delivery for Nigerians.

Continuation of these workshops has been programmed in the up-dated project document and activities and coordination by the C & QC department is recommended above.

CONCLUSIONS

Countries the world over have implemented and are continuing to implement national programs of standardization, certification, and quality control resulting in tremendous national economic progress. As a

specific example, the Japanese have converted their reputation of cheap, shoddy products to a reputation for high quality, precision products at world competitive prices.

It was accomplished by a multi-faceted effort throughout their society, including export inspection laws and implementation; standardization and certification laws and implementation; widespread education through radio and press, in-plant and outside plant training courses, management seminars, industrial team visits abroad; employee motivation for quality including sharing of profits to raise the standard of living of their employees who become company customers; invitations to experts from developed countries, including heeding their advice and taking action to implement corrective efforts; to name some significant efforts in their awe inspiring climb to a world leader of quality products.

It can happen in Nigeria. It will take the kind of effort and co-operative spirit mentioned above to bring it about. What more appropriate time to launch such an effort than the post-era of FESTAC-II with its inspiration to unity of purpose and spirit of accomplishment and influence on a competitive world!

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CAQ STARTS WITH CAD

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INTRODUCTION

Total Quality Control requires that Quality be designed into a product. As computer resources are developed for use in the design activity, the quality function must become directly involved in incorporating its requirements into the design and manufacturing processes generated by Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM). Computer Aided Quality (CAQ) techniques should be incorporated simultaneously with the design of the CAD/CAM data base.

This paper discusses methods for superimposing control techniques on the CAD System while developing thermal analysis, reliability prediction, maintaining configuration control and developing test and inspection programs.

DESCRIPTION

Conversion of traditional design, manufacturing, and quality methods to Computer Aided methods is generally done on an individualized task basis to solve a specific problem. This results in a series of stand-alone programs which require either manual interfaces or special interface programs. Automating on such a basis can result in a very efficient single-step operation that solves the specific problem, but in many cases, complicates the overall interface problem with other functions in the design-to-ship cycle. Figure 1 illustrates the conventional information flow based on manual development of design data.

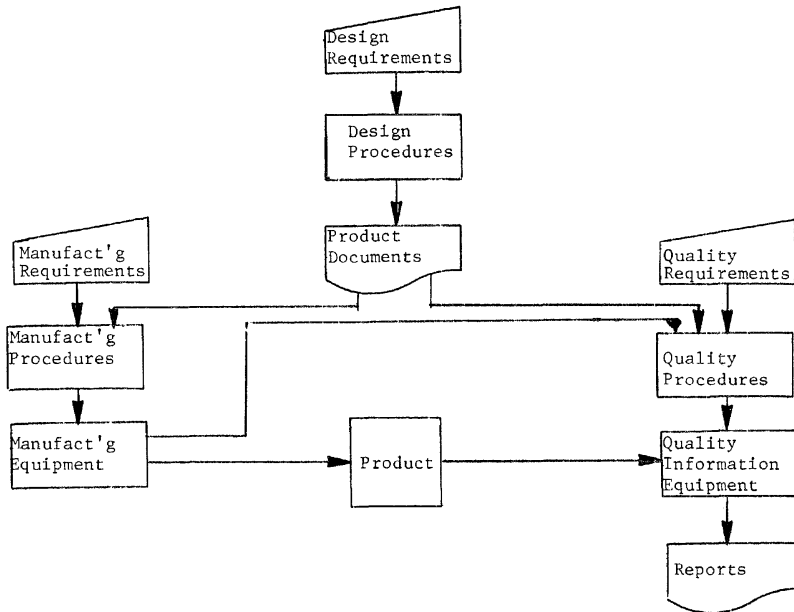


Figure 1: Conventional Information Flow Diagram

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Many steps are never automated for several reasons:

Conversion is not considered to be cost effective.

Traditional operating rules and responsibilities are rigidly applied.

By developing an interactive and functionally integrated automated system, in module form, a real gain in accuracy, productivity, efficiency, accountability, and flexibility can be achieved. Such a system should be based on the following premises:

Everything designed will be manufactured.

Everything manufactured will be quality evaluated.

Manufacturing processes will be quality evaluated.

Quality is designed into a product.

Every step can be automated.

Figure 2 illustrates the modularized interactive Computer Aided System concept. It differs from traditional systems in that it is developed as an automated system that permits manual operations. It is not a manual system with automated steps. It also differs from some CAD/CAM type systems in that its modularity permits each function to retain total control of their areas of responsibility.

The links between modules are designed for automatic communications (hard wire) but can be used with paper tape, magnetic tape, punched cards, etc., as the transfer media. A mandatory requirement is that the I/O format and transmission code be compatible with the communications line requirements. The selection of the communications method is the responsibility of the user of the data.

The key element of the system is the centralized Data Base. This data base is defined by representatives from all functions but is operationally controlled by an independent group. Data contained here is generic in nature with all redundancies removed. Data may be implicit since a computer talking to another machine does not require explicit information. This permits a reduction in paperwork but requires

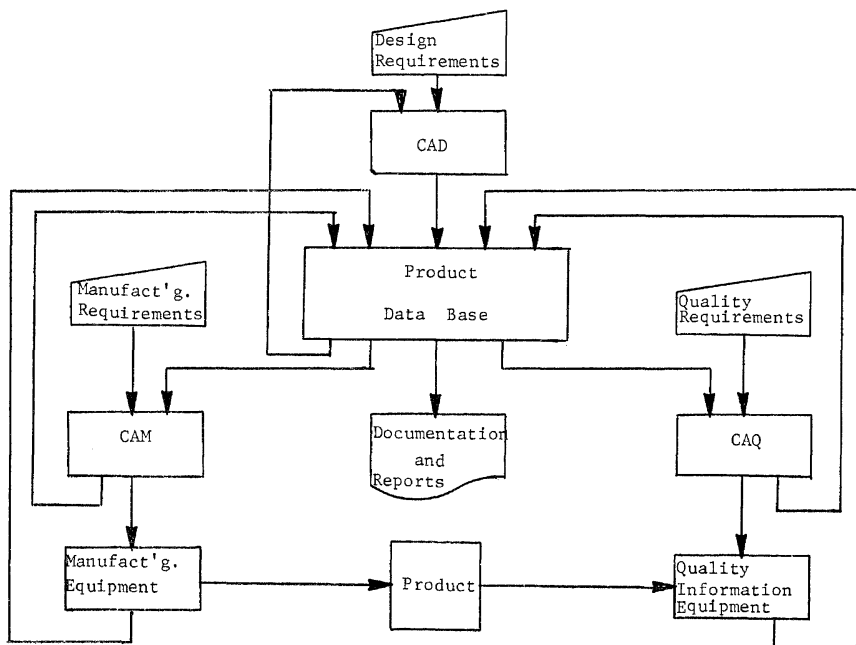


FIGURE 2: Interactive Automated System

that strict revision/configuration control measures be incorporated.

Modularity permits elements to be developed by the responsible organization to any size, in any configuration, and at any time in a logical and controlled sequence. Modules can be bypassed, omitted, or be manual operated without affecting other operations. Operation of a module is controlled by the user thereby providing him with direct cost and efficiency control. Modularity also permits functions to interact in an automated mode by providing timely and accurate feedback. Audit points, information checks, and production "stop" points can be programmed into various modules and stored on the central data base.

Use of the system is illustrated by the two examples shown in Figures 3 and 4. Figure 3 depicts the electrical design through electrical test of a digital printed circuit board. This flow is presently in use at GE-AESD. Figure 4 describes the design through inspection of metal parts. This flow is only partially operational. In both examples, each data base is physically in the same location which is transparent to the user. Strict data base access and content change controls exist.

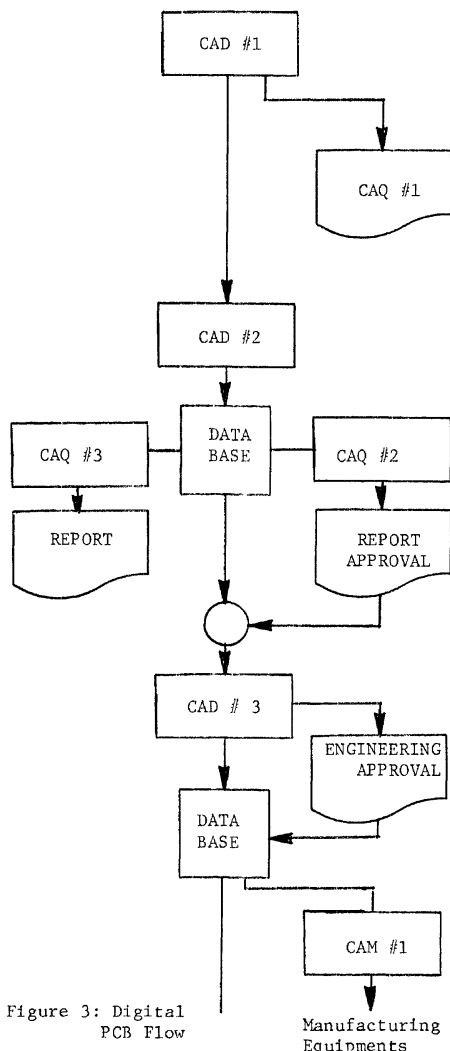


Figure 3: Digital PCB Flow

The digital circuit flow description begins where Engineering selects the electrical components to be used. A complete description of each component is entered onto a computer file (CAD #1). A Quality check is made, via an automatic printout (CAQ #1) which is used to verify either the existence of these components on the Department's qualified component list or that a request for qualification has been processed. If discrepancies exist, appropriate corrective actions are initiated immediately.

Component placement programs are run (CAD #2) with the result placed on the data base. This data is then passed through a thermal analysis program and then through a reliability analysis program (CAQ #2). Reliability Engineering reviews the output of CAQ #2 and must approve the result or further development is not permitted. Concurrently, a component approval report is again generated (CAQ #3) comparing the components listed in the placement program with those on the department's approved parts list. This is done to assure that no unauthorized components have found their way to the design.

The circuit board interconnections are designed via another computer program, CAD #3. Drafting extracts the data via an automated plotter to produce artwork and machining master photo plots. The contact positives made from the master photo plot are checked and approved by Design Engineering. Only when this approval exists can Manufacturing or the Test and Inspection function extract the data.

The manufacturing extract (CAM #1) is actually three separate activities.

1. Develops negatives used to develop the glass plates used in the printed circuits board (PCB) etching process.
2. Develop an NC program to drill the PCB.
3. Develops an NC program to perform the router operation on the PCB.

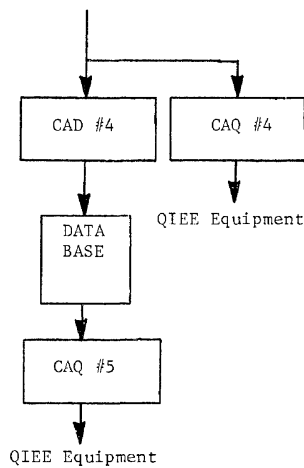


Figure 3: Digital PCB Flow (continued)

Quality Information Equipment Engineering (QIEE) extracts data via programs which design the test adapter and provide an NC program to test the continuity of the resulting PCB (CAQ #4).

Concurrent with the CAM 1 and CAQ 4 activity, Design Engineering develops the final performance criteria by utilizing Fault Analysis Simulation programs (CAD #4) to measure design effectiveness and establish test requirements. QIEE software (CAQ #5) utilizes the Engineering output to develop a test program for use on computer controlled test systems. To ensure thorough testing, the CAD 4 and CAQ 5 operations generally require several iterations early in a new product design before acceptable results are obtained. A significant advantage is the reaction time and the ability to measure the effectiveness of the test to determine all potential faults in the product.

Traceability of all data is maintained throughout by use of revision letters, correction counters, and data base change time and date records.

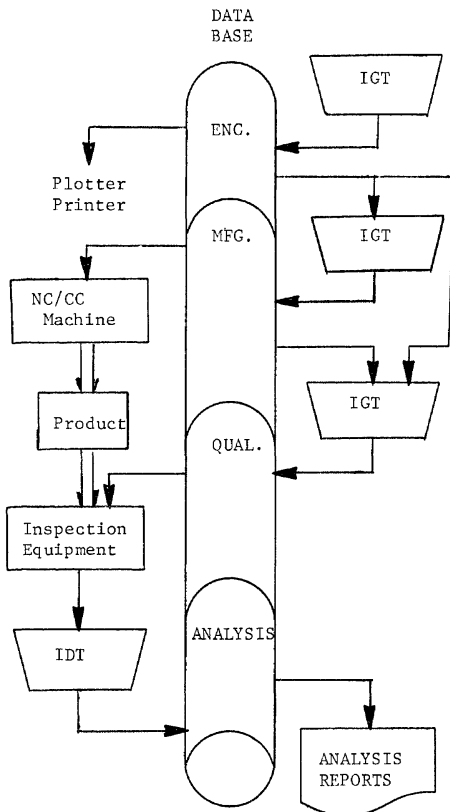


Figure 4: Machined Parts Flow

Machine parts are designed (Ref. Fig.4) using an Interactive Graphics Terminal (IGT). When complete, the design is stored on the product data base which is used by peripheral equipments such as plotters and printers to provide Engineering drawings, parts list, and other required design information. This data base is also used by Manufacturing, via an IGT to add information required to develop programs for use by Numerically Controlled (NC) or Computer Controlled (CC) machines. This additional data is stored on a separate section of the product data base where it and the Engineering data is accessible by the Quality function, using an IGT, for use in developing the program to be used by the automatic inspection equipment. Manual inspections are possible in instances where a terminal is located at an inspection station. This terminal would display the requirements and act as an entry point to feedback results. The Quality requirements are stored on a separate section of the product data base.

Inspection results are collected, either automatically or manually, and transmitted to a separate section on the product data base using an interactive data terminal (IDT). Process and product analysis reports are developed which provide feedback instructions to the machine tools. This feedback is presently manual but automatic operations are in the discussion phase.

SUMMARY

The integration of CAQ is not limited to any type of design. It can be, indeed it must be, included into the total design and manufacturing operations. It should include test and inspection results reported automatically.

The operating benefits of a modularized total system are many and varied. They can be realized only if existing methods, standards, instructions, and organizational responsibilities are considered as starting guidelines and not end goals. The following is a list of some of the advantages identified in the use of such a system at GE-AESD.

- o Provide a common data base for the storage and extraction of data
- o Provide an effective control of data
- o Minimize redundancy of data
- o Reduce schedules (Lead Time)
- o Minimize liaison between all concerned functional groups
- o Consistent interpretation of data
- o Consistency of output (formats)
- o Minimize recurring manufacturing and quality programming
- o Provide back-up operating programs
- o Manufacture to design and standards
- o Quality measurements to design and standards
- o Configuration control
- o Revision control
- o Historical records
- o Quality information reporting - consistent and timely
- o Error checking (designed within manufacture and quality capability)
- o Improved cost assignment and visibility
- o Defect visibility and responsibility assignment
- o Minimize print development and control problems
- o Output extract independent from input loading

LCS 020:70:099

ORCHESTRATION - THE TRUE TEST OF QUALITY MANAGEMENT

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INTRODUCTION

To put my discussion of today's topic, which is "Orchestration - The True Test of a Quality Manager", into perspective, I feel that some introductory remarks about my organization are in order.

The Collins Divisions of the Avionics and Missiles Group of Rockwell International are an over \$200 million dollar organization consisting of three independent Profit Centers addressing separate aviation markets. Each of these Profit Centers has their own Quality Control function and are solely responsible for the quality of their manufactured products. Each of these Profit Centers is also solely responsible for their marketing, scheduling, profit and loss. For this reason each of these Profit Centers have organic Marketing, Engineering and Manufacturing activities and are, in turn, supported by the common support functions of Purchasing, Finance, Personnel, and Product Assurance.

The Quality Control Managers have dotted line relationships to the Product Assurance Director. The Product Assurance Director is responsible for Procurement Quality, Product Evaluation, Receiving Inspection, Component Engineering, Reliability, Product Integrity and Product Assurance Engineering. He is responsible for the overall Quality System and establishes Quality Policies and Standards. He tracks Quality Cost in the four major classical categories of Preventive, Appraisal, Internal and External Failure Costs.

Having established this common data base of information, I would like to address, in the next 25 minutes; the significance of Orchestration; some prerequisites for insuring that it takes place; what should be done to achieve orchestration; what we do within the Collins Divisions to achieve it; the role computer aided techniques play in this effort; and what lies ahead to be done in the future.

ORCHESTRATION - WHAT IS IT

Juran addresses this subject, and, in general terms, states that Orchestration is the coordination, performed by the Quality Manager, of the entire collection of activities through which we achieve "fitness for use", no matter where these activities are performed.⁽¹⁾ In our organization this Quality Manager is the Product Assurance Director.

Orchestration includes the coordination of the Quality aspects of:

- . Receiving activities
- . Materials handling, storage and issue activities
- . Special process activities for fabricating, finishing and assembling our manufactured product
- . The basic in process assembly, inspection and test activities
- . Final inspection and material handling activities
- . Packaging and shipping activities, and
- . Customer services on returned goods

to the extent that internal quality indicators in each of these areas monitor and signal problems and to the extent that these indicators track with our customers opinion of our products "fitness for use". In general terms, "fitness for use" is another way of saying the product is "OK". But, as applied in our customer interface, it also includes understanding how the product is used and how that usage relates to non-verified rejections.

PREREQUISITES THAT PERMIT ORCHESTRATION

The prime prerequisite to the ability to even possibly perform this task is a "commitment by top management to the quick detection of quality troubles at the earliest possible point in the process after defectives have been generated".(2) Why? Not just because intuition tells us that rework/repair has a degrading effect on the quality of our products, but, in terms most popular and meaningful to management, it is expensive and results in a direct reduction of potential profits.

ORCHESTRATION - THE IDEAL

For the sake of this discussion let us consider what can be considered to approach an ideal.

The Ideal (Figure 1) would be to have a fully automated system that provided, as product flowed to the customer, feedback and positive corrective action on identified discrepancies at the key automated inspection and test points throughout the processes with the resultant plot of defects being attributable to truly random part failures. I mentioned earlier that the commitment by management should be there, not only because early detection of defects results in better quality, but early detection of defects results in a cheaper defect, a less costly rework or repair. As an example, it has been our experience that an "electrically defective part" found within the receiving inspection activity saves a \$12.00 rework cost that would have been expended if detection occurred during assembly or test (not counting the Part Material Costs). We have also observed that a detected assembly inspection workmanship defect cost \$5.00 to repair; test rejections, during module test, costs about \$12.00 to repair; final radio rejections cost \$10-20/repair (unless it occurs during burn-in of the end item at which time it would cost \$27.00 to repair); and, last but not least, customer warranty rejections range from \$60-\$250 to repair depending on equipment complexity and defect. As one can see, there is substantial financial motivation to reach for the ideal.

WHAT CAN BE DONE?

Needless to say, we within Collins Avionics Divisions have not, in our operation within Avionics and Missiles Group reached the ideal, however the closer we move towards that objective the more we have realized.

- . Our dependence on computer aided quality, and
- . Productivity gains which earn us an improved return on our investment.

The true test of Manufacturing Management is the establishment of a functioning entity that balances the needs for long term profitability, in terms of on going sales, with the needs of a quality product in the market place.

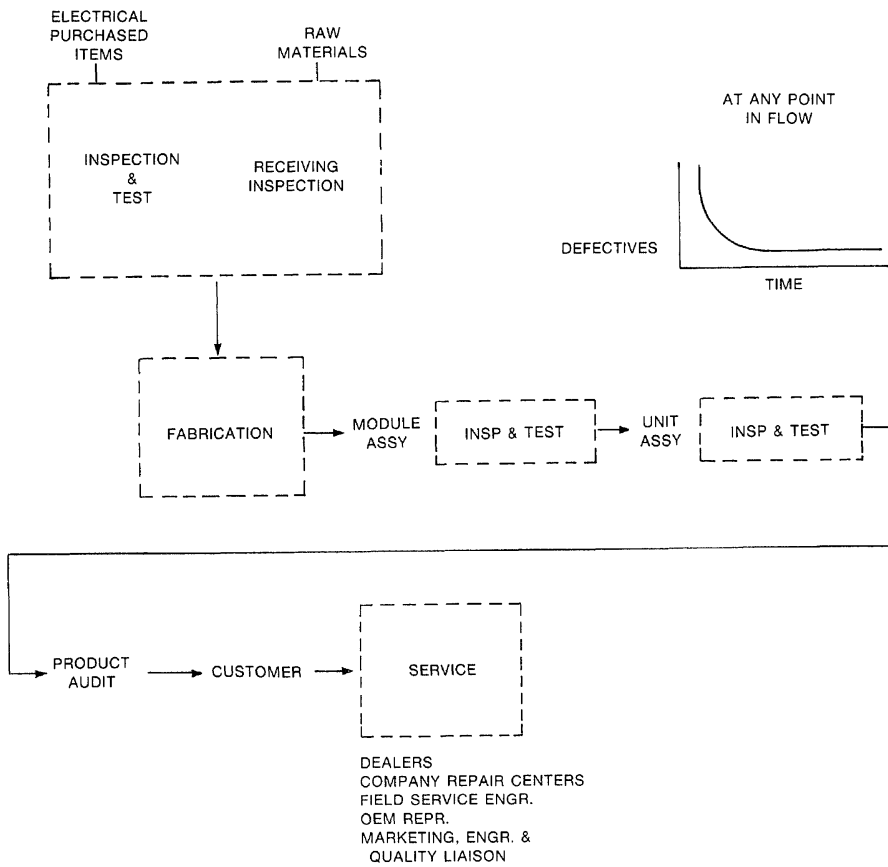
The true test of the Quality Manager responsible for overall Quality Systems definition and policy is understanding what affects on going sales from a quality viewpoint, communicating these needs to General Management, and orchestrating the activities of the company that can contribute significantly.

Let us look at these activities. It has become apparent to us that, as the business grows, as technology continues to become paradoxically simpler but yet far more complex, we are but one of many "meters" among the many manufacturing concerns that both stimulate that continued technological growth and, at the same time, assist in the harnessing of it.

Let me expound on this briefly and then, having done so, tie together the analogies used so far in this discussion.

→ PRODUCT FLOW
(AUTOMATED WITH REAL TIME)
FEEDBACK

IDEAL



← FEEDBACK FLOW
(AUTOMATED WITH REAL TIME)
FEEDBACK

FIGURE 1

Manufacturing Businesses, through recognition of the market place needs, initiate R&D activities that capitalize on new uses of existing hardware, and are the catalysis for new technologies. We either design and develop these technologies and resultant products, or we subcontract the effort as required. Regardless of the choice, we recognize that it is not until after multiple attempts, or many trial and error type situations, that the product becomes usable or economically feasible.

Through Receiving Inspection test and inspection capabilities, through controlled process inspection and test, through machine controlled assembly, through the analysis of observed anomalies in each of these areas we identify problems and seek implementation of corrective actions. We meter the processes and act to control.

HOW DO WE DO IT?

We do this through techniques that are also the outgrowth of technological advances. Computer aided or computer controlled assembly, fabrication, inspection, and test machines and equipment supply us the data we need to continually assess and improve.

If we had not tested every IC utilized within our equipments, we would not, nor would the industry in general, have seen the rejection rate of received products drop from four percent to half of one percent. This is why today we test all diodes and transistors. Not because product received is intentionally unsatisfactory, but because all defects and defectives have not been eliminated and elimination of defective items within receiving is much cheaper, as noted earlier in our discussion, than the elimination at an assembly or end item level.

But receiving data is only part of the picture. Through semi-automated assembly, errors are reduced. Through automated inspection and test undetected errors, not caught in Receiving Inspection or earlier inspections and tests, are uncovered. What percentage distribution of these problems should be caught at Receiving? How many rejections are design related? What problems observed in the field are vendor or manufacturer design oriented?

Orchestration assures answers to these questions and actions to accommodate corrections which result in happier customers and on going sales.

OPPORTUNITIES FOR THE CONDUCTOR

New products (i.e. CMOS, LSI, Bubble Memories) will require continued evaluation during their maturing process. With their advantages of reduced size and volume and increased capability, will come the basic problems of their complexity, when trying to determine the cause of rejection.

As automated techniques take advantage of other technological developments in the form of "mini" and "micro" computer and processor capabilities, the tempo for defect information transfer will continue to escalate.

Herein lies the opportunities as well as challenges for the conductor. The Quality Systems of the future must, to keep pace with the technology of the future, be responsive, dynamic and orchestrated. It must, of necessity

- . provide continued receiving adjustment
- . provide identification of undesired effects as soon as possible in the process flow
- . provide initial to final end product performance monitoring capability
- . provide sensitivity to customer anxieties
- . provide professional vendor coordination relative to product deficiencies.

Who is the conductor of this symphony of activities? With whom will these challenges lie? Who will be the object of this true test? You are! That's who!

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- (1) Juran, J. M. "Quality Control Handbook", Third Edition 1974, McGraw Hill Co., New York, NY pg 2-11
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LCS 330:10:439

QUALITY: A CORNERSTONE FOR MANAGEMENT

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Out of the business sector of western civilization a distinct social group has evolved with special interests, characteristic economic views, its own sense of logic, and an affinity for the tried and proven way of doing things. This group consists of those people who conduct, direct, guide, control, and have charge of a business enterprise. What has evolved is management.

It should be noted here that the term management refers to a group of people; hence, it is a collective concept. Concisely, management is the collective power or leadership of a business. This leads to an intriguing question: Can management survive? To answer the question one must identify the determinants of management's survival.

In any business the survival of management depends on the continual economic success of the enterprise. The measure of economic success is the surplus of the enterprise without regard to the distribution of the surplus. In financial terms, surplus is the amount by which income exceeds expense. This surplus is often

considered net income or profit.⁽¹⁾ Income which generates a surplus is profitable income. It follows that the continual economic success of an enterprise requires profitable income. There are a variety of income sources. Some of them are: sales, revenue, private contributions, royalties, rents, leases, subscriptions, stock dividends, interest collections, and tax collections. In any case the successful enterprise must establish and maintain a composition of income which generates a surplus over all the expenses of doing business.

If there is no surplus and the expenses of a business continue to exceed its income, the resources of the enterprise become exhausted, and there no longer exists the power to stay in business. Since management is the collective power of the enterprise, management's survival will be determined by its power to generate profitable income. This also implies that if over a period of time expenses rise, management must demonstrate the ability to increase income.

What does quality have to do with profitable income or the survival of management? This needs some clarification. Think of fitness for use. In purchasing an item or retaining a service, while comparing prices, you make your selection normally based on how fit you think a particular choice will be for your use. What you are thinking about at that time is the quality of the items or services considered. Quality means fitness for use. When I refer to quality in what follows, I mean fitness for use.

In order for management to survive it must be aware of that which produces profitable income. Management not only needs to be aware of it, it needs to establish and maintain it. What is it? Basically, income is derived through the trade of goods and services. The law of supply and demand determines the amount of income that can result from a particular trade. This is the crux of the matter. Demand is the amount of people who have both the desire for a commodity and the purchasing power to acquire it. The extent of this desire depends on the quality, which the consumer perceives.

From spring 1970 until the summer of 1976 the United States experienced one of the longest economic recessions in its history. It seems Americans were spared most of the indignities during this period that had been suffered during the Great Depression from fall 1929 through spring 1935. However, Americans had a tremendous cushion in the early 1970's, which didn't exist in the 1930's. By 1970 the United States had the largest financial reserve that any society has ever been able to amass: Thirty-four years of accumulated surplus funds in Social Security pensions, unemployment insurance, and welfare programs. On the eve of America's Bicentennial, Americans were becoming well aware that they had practically exhausted this reserve.

Shortly after the recent recession got underway, in 1971 an anomaly occurred: The beginning of the bicycle boom in the United States. It lasted until August 1974, and then the bicycle business followed the rest of the economy -- down! down! down!

For over three years the demand for bicycles exceeded the supply by a considerable margin. During that period the average quality of a bicycle sold declined considerably. The customers wanted bicycles and weren't going to argue about color, a poor paint job, a sloppy looking weld, or even a missing part. I know the situation because I bought a bike during that period, which was before I got directly involved in that industry. I waited nine weeks for the bike I wanted, but settled for less when I was told that my order would be delayed indefinitely. I then looked for a bike in ten different stores.

The best bike I could find not only displayed a few examples of shoddy workmanship, it came equipped with a 3-speed gear mechanism, that began malfunctioning within a week. The bike was purchased assembled and without any instructions or guarantee. So, when I took it back to the store, the department manager responded with, "The only thing I can do is replace it, but it will cost you another twenty dollars."

It was a genuine, first class rip-off! I passed my opinion to the store's upper management and to that of the bicycle manufacturer. The manufacturer never responded, but the store did, granting me twenty dollars credit on my account. In turn, I have responded by still doing business with that store and resisting the use of any product of the bicycle manufacturer.

When the bottom fell out of the bicycle market, it was not surprising to observe that business fell off rather proportionally throughout the industry. In the mind of the consumer there was little difference in the competitive commodities. Had one bicycle manufacturer consistently produced higher quality bicycles, it would have gained considerable market share, while its competitors' business declined more precipitously. There are fewer bicycle manufacturers today than there were back in the summer of '74. There simply was not enough quality in the first place to produce a profitable income for those companies that failed to survive.

Normally, people don't plan to fail. But often they do fail to plan! In business, success usually comes through planning and that includes planning for quality.⁽²⁾ In the marketplace, if there is any competition at all, the commodity most suitable for use is the commodity in highest demand.

There are many people with functional responsibilities and power over quality, who have been trying to sell management on the merits of quality. Most of these people are themselves part of management for some enterprise. This brings us to a paradox -- two of them in fact.

First, management is regarded as the leadership of an enterprise. But the participants in the managerial ethic often find themselves so wrapped up in compromise, getting results, status and identifying with the establishment of the organization (which is usually bound in tradition), that true leadership seldom surfaces. There is a reason for this. Leaders forge new direction, new ideas, new methods, and inventions. Managers on the other hand are inclined to control matters according to proven direction, proven ideas, proven methods, and proven products. If either of the two is going to come up with

something better than before, it will be the leader (3)-- because it wouldn't be something better than before if it had already been proven. Those, who lead, marshal the necessary forces and use their ability to actually test the new and better concept. The leader takes the risks. Good planning can minimize the risks and maximize the potential for a new concept.

The second paradox is that often the quality professional is a part of management, but tends to mentally exclude himself from management by trying to sell management on quality. By this I mean, instead of taking charge and leading, as a part of management, this individual tends to consider himself separately and that his task is to sell those who have the power to establish and incorporate the philosophy and policies related to quality. This usually leads to frustration by the overwhelming sensation that the inertia of the organization is directed towards maintaining the status quo. Changes of philosophy and policy are best achieved through positive leadership.

Positive leadership in the managerial arena requires an attitude of participation, authority, responsibility, good communication, attention to human behavior, and a willingness to venture for higher achievement of the enterprise. From the standpoint of management's survival, there are several business organizations that already have adopted philosophies and policies which strongly enforce quality and the pursuit of excellence. Sometimes they have been developed by top management and trickled down, and in other cases they have surfaced through the courageous leadership of middle managers in the quality disciplines.

It revealing to compare the performance of enterprises strongly oriented to quality vis-avis that of those which reflect little or no attention to quality. It is not my intention to name organizations that fit into either category. Research in this area reveals two phenomena. The first is that those corporations, schools, hospitals, clubs, and so on, which fail, seldom have any pronounced quality objectives or associates specifically responsible for obtaining quality objectives. The second is that those organizations which continually set strong objectives and are so well organized, as to routinely meet these objectives, out perform their competition in the long run. The latter are the enterprises which provide the goods and/or services most frequently in demand. This demand is the source of profitable income and provides the power for management to continue with the enterprise.

Consumers around the world are becoming increasingly aware of quality and where there is a lack of it. The result is that in many democratic societies, where consumers feel that free enterprise is not properly attending to fitness for use, they are authorizing their governments to impose regulations that will mandate the attention. In other words, if management does not plan to take charge of quality, it appears the government may get the power to do so. In many cases where this has already happened the expenses of the enterprise survived, while the enterprise did not - neither, of course, did its management.

The place to start with quality is in considering the objectives of the enterprise and formulating clear statements regarding quality that: Will provide the basis for any related decisions and explain

what is expected. In developing or revising quality policy the following factors should be considered:⁽⁴⁾

1. The level of clientele in the market pursued.
2. The position of leadership that the enterprise is to strive for versus competition.
3. Consumer safety, product liability, etc.
4. Availability, reliability, and maintainability of your product or service.
5. Emphasis between conformance to specification and fitness for use.
6. Product (or service) reliability and initial price relationship.
7. Whether to optimize the costs of the user or producer.
8. Reliance on controls by people or by systems.
9. Line or staff responsibility for quality planning.
10. Involvement of vendors and/or clients with the quality team.
11. The role of top management in quality planning and assurance.
12. Delegation of quality planning, assurance, and control authority.
13. Emphasis on recognizing and reinforcing employee behavior which supports the quality policy of the organization.

Management's statement of policy and adoption of philosophy - directly concerned with quality - is the starting point. This places quality attitudes in the desired perspective. It will serve as the mortar that will hold quality in the position that the enterprise needs for profitable income. This establishes quality as a cornerstone for management.

As indicated, the agreement on quality philosophy and the related statements of policy are the starting point. Now the quality concept has to be put into action, which demands more leadership. This implementation requires planning, direction, organization, communication, experimentation, inspection, and control. Yes, inspection and control. The reference here is not merely to the kind of inspection and control that is incumbent upon the individuals with the word "inspector" in their titles. Specifically, management must inspect performance to the quality objectives, direct changes when quality objectives are not being met, and reinforce behavior leading to the achievement of these objectives.

This kind of leadership - concerned with quality - of an organization can result in higher degrees of consumer acceptance, lower selling expenses, lower operating expenses, and attention to breakthroughs - all of which enhance the potential for profitable income, the success of the enterprise and the survival of management.

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LCS 300:10:000

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It is now more than seven years since Appendix B to 10CFR50 was formally issued as federal law by the then AEC. Since this regulatory requirement was first advanced, company after company has scrambled to develop and implement QA auditing programs in response to Criterion 18 of Appendix B.

As you will quickly realize, I am a firm proponent of QA auditing. When executed with the strength of knowledge derived from training, experience, preplanning and professionalism, a comprehensive QA audit program can be an invaluable asset to a company.

Recognizing the need for management support, how does one gain this valuable commodity? The answer is through the logical presentation of, and education to the applicable regulatory requirements and the benefits which can be derived therefrom. An important consideration in obtaining this necessary backing is the credibility of the individual or individuals advancing the QA auditing concept. The need for maintaining this credibility after program promotion and during program implementation is paramount. Loss of credibility will quickly translate into loss of management support and the start of a vicious downward spiral. Given top management support, the necessary funding and staffing requirements can be developed and approved.

I submit that it should be every auditor's fervent goal to some day be able to perform a thorough audit without finding a single significant finding. Although it has yet to be my personal experience to achieve such a revelation during an audit, I have heard the occasional isolated sounds of an auditor who has entered such pearly gates.

The notion that an auditor must have findings to justify his job is unacceptable to me. Auditors found to exhibit this personal philosophy should be exorcised from the program, auditees who fear such an approach should be counselled and assured to the contrary; and, programs which endorse such a backward concept should be scrapped, together with its misguided management.

PROGRAM'S BENEFITS

There should be little debate on the regulatory necessity for independent review of quality affecting activities through audits. The need to continually assure the protection of the health and safety of the public is a responsibility which cannot be overemphasized. It is vital in maintaining nuclear power as a viable, safe form of energy. However, I believe there are additional motivators for enacting a thorough, well-managed, professional QA auditing program.

One of these motivators is the realization that often the only direct interface a contractor or vendor has with the client, is during client's audits of their activities. This could be true whether it is a reactor vendor auditing one of its suppliers, an architect-engineer auditing a vendor, a utility auditing the architect-engineer or the Nuclear Regulatory Commission inspecting the utility. The potential impact of this "flag waving" opportunity is significant, since the image of the auditing organization could hinge almost entirely on the manner in which the audit team executes its responsibilities. The extent to which the auditors are professionals could affect the attitude of the audited company toward the project as a whole. Immeasurable harm or benefit can be derived from the experience - I have seen both. The positive reaction has never failed to impress and please me. The negative situations always make me want to shake the auditor by the shoulders to reemphasize the impact his actions have.

An effective audit can cause the audited organization to change its attitude in addition to its behavior. This is most important, for behavior only reflects what we do - attitude reflects how we feel about what we do - one's commitment, if you will. An effective audit can also place emphasis on what is important, and thereby reduce the amount of effort or attention being placed on extraneous or insignificant activities - activities which are not contributing toward the quality of the service or product.

A very important benefit of a comprehensive, well-planned, fully executed and documented program is its capability to satisfy the third party auditor who is auditing, inspecting or surveying your company.

If your own internal auditing efforts are weak or incomplete, expect the third party auditor to penetrate deeper into your company's activities. If your external audit efforts are inadequate, expect the third party auditor to consider accompanying you on an external audit, having you increase your audit frequency, and/or having other incremental impacts on your program. Conversely, a sound QA auditing effort will establish credibility with the third party auditors, resulting in more favorable reports on the company's management and activities; a very positive cause-and-effect relationship.

Management's satisfaction with a credible program may lead to the auditor's involvement in investigating "those sensitive" situations which occur from time to time in an organization. Whether this involvement takes the form of specific participation by the QA auditors or simply using their techniques, it further demonstrates that management perceives the QA audit process as an effective management tool which can be tailored to investigations, whether they be QA-oriented or not. The use of auditing techniques in typically non-QA areas is a vital theme. A proven auditing system can result in other organizational components emulating key features of the program, such as planning techniques, reporting formats, scheduling methods, briefing session philosophy, status and commitment tracking, etc. This form of flattery will increase the level of understanding and acceptance of the overall QA program, thereby strengthening the QA effort.

FLEXIBLE SYSTEM

Auditing is a flexible technique and as such can be easily applied to a variety of areas. Examples of this application are financial auditing, operational or management audits, administrative reviews to determine the facts surrounding particular situations,

whether they be EEO discrimination claims, potential personnel disciplinary cases, environmental infraction allegations, safety investigations or other fact finding missions.

The Comptroller General of the United States notes in the forward to a pamphlet entitled "Auditors Agents for Good Government," that "Auditing is often considered... to be primarily concerned with the proper safeguarding of funds and property. Actually, this is only part of the concern of auditing."¹ The Comptroller General goes on to state that..."Auditing can be very useful to those...who recognize its potentials and use its reports. It can, for instance, alert them to potential problems so that they can make programs work effectively and correct inefficiencies and uneconomical practices before serious or even irreparable harm is done."²

During my association with the nuclear industry, I have seen audit concepts successfully function in such non-QA related situations as a review of conflict of interest charges, fraud allegations, assessment of cause and responsibility for a fish kill, compilation of facts regarding contract disputes, determination of need for specific management systems refinement, and so on.

Additionally, I have seen audits effectively performed on such non-routine QA subjects as a review of disagreements between surveillance agency personnel and the personnel of the manufacturing company being surveyed, a review of statements quoted in newspaper articles by contractor's personnel regarding QA, reviews of questionable material suitability charges, and others.

These experiences clearly indicate that audits are flexible, viable options which management can, should and frequently does rely on to determine the effectiveness of its operations.

SPECIFIC EXAMPLE

To further emphasize the usefulness of this management investigative tool, I would like to cite one example in particular. The case in point is the North Carolina Utilities Commission ordered audit of Carolina Power & Light Company (CP&L). This audit, or study, was an eight-month evaluation of CP&L's management systems, procedures, and performance. CP&L, a company whose hallmark is a progressive style, open communications and responsive management, issued a pamphlet entitled "What Kind of Job is CP&L Doing?" This document highlights the management performance study which they had undergone by an independent, outside consulting firm and provided its' customers, shareholders and employees with a concise, accurate summation of a 700 page report.

In the pamphlet, the purpose of the audit is stated as follows:

"The objectives of the study, as stated by the auditors, were to provide an impartial, professional assessment of CP&L's management and operating efficiency, to identify opportunities for improvement, and to provide recommendations for achieving improved, more cost-effective operations."³

Commenting on the report, CP&L's chairman notes in the preface to the pamphlet:

"The results of the audit show that CP&L is operating efficiently and that we are doing a good job for our customers. As in any large organization, CP&L has areas for improvement. Where the potential for improvement has been identified, we have initiated appropriate action."⁴

The pamphlet concludes by noting:

"The report pointed out that CP&L has continued to be responsive to major changes - in economic conditions, in regulatory climate, in technology -

¹Auditors Agents For Good Government, Audit Standards Series Number 2, United States General Accounting Office, United States Government Printing Office, Washington, D.C., 1973, p. i.

²Loc. cit.

³What Kind of Job Is CP&L Doing?, Carolina Power & Light Company, Raleigh, 1977, p. 2.

⁴Ibid., p. 1.

and has been able to modify its organizational structure and operating functions, sometimes quite drastically, to adapt to these new conditions."⁵

In summarizing the findings, the outside auditors observed:

"The interest in and resolve of the top management during the course of the study in moving directly and promptly on opportunities for improvement provides assurance to the consultants, and the commission of CP&L's continued resolve to carry out these plans."⁶

The example of CP&L underscores the concept that audit programs can provide management with the opportunity to assure that vital activities are being performed satisfactorily, efficiently and in accordance with commitments, thereby maintaining the company's internal and external credibility.

MANAGEMENT PRINCIPLES

Another way of realizing the value of the audit function to goal-oriented management, is to select a few key phrases from criterion 18 of 10CFR50, Appendix B entitled "Audits". This approach results in phrases like "A comprehensive system....to verify compliance....and to determine effectiveness.... . Audit results shall be documented and reviewed by management.... ." Aren't these the basic managerial principles of monitoring against goals, feedback, follow-up and management action?

In essence a QA program is a comprehensive management system, with audits representing certain basic elements of the overall management process. The concepts of planning, defining authority and responsibility, setting goals, integrating implementation, measurement, feedback and corrective action are all represented in an effective QA program; and can be reviewed through an auditing function.

Certainly audits are time consuming. But as the venerable Dr. J. M. Juran notes regarding audits in his book entitled "Quality Planning And Analysis," "All this takes time. This is the price one pays for the realism of facts over the drama of opinions."⁸

SUMMARY HIGHLIGHTS

In summary, to develop a useful, comprehensive QA Auditing Program, three fundamental ingredients are required:

- Credible QA personnel to advance program.
- Top management support.
- Selective hiring of QA audit staff.

Given the establishment of a well planned, professionally staffed QA Audit effort, program benefits can be realized in several areas such as:

- Owner's successful representation in outside firms.
- Improved attitude and behavior by others toward QA.
- Emphasis focused on salient points.
- Increased credibility with third party.
- Audit techniques used in non-QA areas.

In conclusion, I content that the limits to which QA auditing as a system are of benefit to management is quite simply a function of the credibility and resourcefulness of the QA people, and the commitment and perception of their management.

⁵Ibid., p. 9.

⁶Loc. cit.

⁷Quality Assurance Criteria For Nuclear Power Plants and Fuel Reprocessing Plants, Title 10, Code of Federal Regulations, Part 50, Appendix B, General Services Administration, Washington, D. C., 1977, p. 301.

⁸J. M. Juran and Frank M. Gryna, Jr., Quality Planning and Analysis, McGraw-Hill Book Company, New York, 1970, p. 563.

GENERAL PURPOSE A.T.E.'s ARE NOT FOR EVERYONE

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INTRODUCTION

The advent of computers and microprocessors have brought a tremendous expansion in the types and capabilities of automatic test equipment (A.T.E.). A.T.E.'s are sought after because they provide cost savings:

- Repeatable Testing
- Minimum Operator Training
- Faster Testing
- Faster Diagnostics
- More Complete Testing

The computer directed general purpose A.T.E. provides printed circuit board (P.C.B.) manufactures with flexible and repeatable testing means; but is it what he needs? The following discussion deals with this by describing the basic types of A.T.E.'s, a review of potential pitfalls, and outlining a method for equipment selection.

TYPES OF PCB A.T.E.'s

Before an ATE is selected, a review of the basic types of ATE's will provide a prospective on the options available.

1. General Purpose A.T.E. - Tests digital, analog and hybrid assemblies.

Digital diagnostics is directed to a node or a component.

Analog diagnostics usually to a functional area.

Programming usually through the aid of circuit simulation for digital and manual for analog.

Investment:	Machine	\$200K to \$300K
	Fixtures	\$1K to \$5K
	Programming	80 to 160 hours

Advantages:

1. Capability of testing a wide variety of PCB's (Digital, Analog, Hybrid)
2. Fully directed testing and diagnostics which results in minimum operator training and skill.
3. Measurable test completeness or comprehension.

Disadvantages:

1. High investment in hardware and software.
2. Due to machine flexibility, extra caution must be exercised to prevent production bottlenecks

Sources: (1) 1. Computer Automation, Gen Rad,
Hewlett-Packard.

2. Incircuit Tester

Tests for shorts, opens and component function on the PCB through a "bed-of-nails" fixture which accesses many or all of the interconnection points.

Diagnostics to the component.

Programming is done with automatic program generation with manual timing.

Investment: Machine \$60K to 90K
Fixtures \$ 7K to 1.5K
Programming 20 to 60 hours

Advantages: 1. Low fault isolation cost
2. Low programming cost
3. Excellent for bring up yield on a more expensive functional tester.

Disadvantages: 1. Limited functional testing
2. Complex fixture generally required for each PCB.

Sources: (1) Faultfinders, Testline, Zehntel

3. Digital Comparison Tester

Tests a digital PCB by comparing the boards reaction to stimuli with that of a known good board.

Digital diagnostics to a component or node. Requires an operator to use a logic diagram.

Programming is done by manually selecting pulse sequences on a known good board.

Investment: Machine \$15K to \$70K
Fixture \$1K to \$ 3K
Programming 40 to 80 hours

Advantages: 1. Low initial investment
2. Fast PCB screening capability
3. Low cost programming
4. Tests can be performed at speed

Disadvantages: 1. No analog
2. Technically competent operator to isolate faults.

Source: (1) Fluke

4. Dedicated Automatic Tester

Custom built equipment using a microprocessor to test specific board types. Typically developed by the manufacturing house to fill a specific volume of test requirements.

Programming is manual

Investment: Machine \$15K to \$30K
Fixtures Included in above
Programming 20 to 120 hours

- Advantage:
1. Custom built to provide accuracies that are not available in commercial equipment.
 2. Repeatable test for complex PCB (particular importance in a long step by step test sequence in which the operator could omit a step).
 3. Low cost if it potentially saves the investment of another General Purpose A.T.E.

- Disadvantage:
1. Equipment life generally tied to product life.

The purpose of the above listing was to show the wide variations of machines that are available for consideration. One, some or all of these might have a place in your manufacturing line.

(1) Sources are not meant to be all inclusive but suggest typical manufacturers.

A.T.E. PITFALLS

There are an infinite number of problems that one can get into when using ATE Technology. However, for your consideration, a brief listing has been prepared of common problems which if planned for can be controlled. Without planning, the results can be painful to the unsuspecting user.

1. The first and one of the most significant problems can be best described as "After spending \$XXX thousand, it won't test more than three card types in the first six months"? It must be remembered that a computer directed tester is only as smart as the program. This leads you to the Instrumentation Programming Engineer who develops the software. This manpower must be provided to get the programming results in the time expected. Using an outside source, such as many of the ATE producers provide, does not fully solve the software problem, but it is excellent for helping with peak loads. Considerable coordination on what is wanted in the program is required between the outside source and your in-house programming engineer. Thus, machine utilization may be low unless adequate software plans are made at the time of equipment purchase.
2. The next problem is called the "bottleneck". This is the description of what happens when your production flows through the ATE and due to machine downtime, testing volume, or programming debugging load, there are not enough hours available to accomplish that which is required. There are two major contributors to this pitfall:
 - a) Being so excited with the capability of the new machine, one starts putting everything possible on it. The result is as the volume picks up, the machine becomes loaded with work that in many cases should be done by lower cost dedicated testers (manual or automatic).
 - b) Don't place on a general purpose ATE one or two PCB's that consume most of the machine time (due to volume and test time). This wastes the money spent to get versatility. Consider a dedicated ATE for cases of this nature.
3. This one is affectionately known as "make it work but don't touch it". The interpretation of this statement is one test program is not working but the engineer can not get on the machine because production is busy testing other needed units. This problem becomes more dangerous as more and more programs are operating on the ATE. It must be remembered that besides software development, machine time will be required for periodic production problems due to machine failure or components from a new vendor causing unexpected results during testing. The control here is to forecast workload and establish production testing on second and third shifts. Also, an off line software development machine (a standard machine less PCB drivers receivers or stimulus sources) can also help lighten the load on the production ATE.

4. The last of the insidious problems is "now that the PCB is rejected, what do I do with it"? Sometimes the test engineer would like to tell production but the real solution is to provide manual diagnostic equipment. This is not always necessary but should be kept in mind for diagnostics that lead you to an area rather than a specific problem.

A.T.E. SELECTION

When determining what type of ATE is needed, a critical review of what are the test requirements must be done. The following list should be included in any effective review plan:

1. Estimated Product Life - Short product life will mean an ATE investment is not practical. Where long life is expected, the product testing and diagnostics investment can be high and still return excellent savings.
2. P.C. Board Type - The types (Analog, Digital, Hybrid) of PCB to be tested must be known so that machine capability can be determined.
3. P.C. Board Volume - This permits establishing priority of which gets programmed first because of payback. Also, where the PCB gets tested. Remember the pitfall of one or two cards tying up a general purpose ATE.
4. Product Outgoing Quality - This is the consideration of the consequences of a bad PCB going undedicated to the next higher level of assembly. In some cases, a very complete second level test is performed and if faults get through, they can be detected. The feedback may be used to tune the PCB test program to improve the test comprehension. However, there are cases where ATE test is the final verification and direct shipment to the customer will occur. In these cases, careful consideration to the test comprehension must be done from the start.
5. PCB Functional Requirements - The functional requirements of the PCB such as accuracy, number of tests to be performed, types of signals, etc. are needed for selecting the make-up of the A.T.E.
6. Operator Interaction - Pot adjustments and switching are common operator interactions. These can waste ATE time and in these cases, it may be better to use a manual tester. A dedicated ATE could also be considered if the volume and test difficulty justify it.
7. Test and Diagnostic Time - Both of these must be considered along with the expected yield so that an accurate estimate of machine loading can be established.

Now that the test requirements have been gathered, the criteria for the test must be placed into "must" and "want" categories. The definition on the "must" should be as precise as possible because this decision says that when reviewing a piece of equipment, if it does not comply, it's out. The "wants" should be weighted as to importance to your application.

Attachment I shows an analysis used for the selection of a general purpose ATE for Honeywell, Process Control Division. This project started with a list of twenty-two equipment suppliers. These were quickly reduced to four vendors because the others did not meet all of the "Musts".

Once the scope of the investigation has been brought down to a selected few, it is recommended that a representative PCB be given to the top candidates so they can demonstrate their capability. This approach provides a good prospective on software and hardware performance; how difficult is the machine to program and how does it respond to the program. Care must be exercised in analyzing the software effort because next to the machine investment, the programming development is the most significant cost encountered.

After witnessing each vendors performance, a KT(2) chart should be prepared (Attachment II). Each attribute being considered should be weighted based on its importance to your specific needs. In this example the weight ranged from 2 to 10, where 10 was the most and 2 was least important. Then each vendor should be rated on how well his machine fulfils each attribute. A perfect rating was 10 and poorest rating was 2.

(2) The Rational Manager by Charles Kepner and Benjamin Tregoe

Thus the weighted performance for each machine is the product of the attribute weight times the machines weighted compliance with that attribute.

Example Calculation for Cost Attribute:

Weight - 6 (Selected as medium importance)

<u>Vendor</u>	<u>Cost</u>	<u>Best Price Performance</u>
A	\$236.4K	7
B	\$310.4K	4
C	\$292.2K	5
D	\$312.9K	2

Weighted Performance for Cost is:

<u>Vendor</u>	<u>Weight</u>		<u>Performance</u>		<u>Weighted Performance</u>
A	6	X	7	=	42
B	6	X	4	=	24
C	6	X	5	=	30
D	6	X	2	=	12

This analysis is continued for all attributes considered. Then each machine vendors volume is totaled. In the example in Attachment II, vendor C with 495 points did the best job of meeting all the attributes.

The attached flow chart (Attachment III) shows what Honeywell PCD does in their testing of the newly released Total Distributed Control (TDC-2000) product line. P.C.B.'s are assembled, wave soldered and then pre-screened on an incircuit tester for shorts, opens, and component problems. The cards then move to one of five different testers depending on the testing requirements for the board. There is also a system test which provides feedback on how effective the PCB testing has been.

CONCLUSION

This review showed the various testers available and depending on the specific manufacturing needs, the general purpose ATE is not for everyone. The decision of how to test is primarily one of economics - cost of equipment, cost of fixtures, cost of programs, cost of finding a failure at a later level of testing. There is no one correct answer. The best solution is that which fits the manufacturing needs of your operation.

LCS 770:40:436

ATTACHMENT I
GENERAL PURPOSE A.T.E. ANALYSIS FOR HONEYWELL, PCD, FT. WASHINGTON, PA.

MUST	A	B	C	D
1. Delivery 10/1	120 to 150 days	120 days	90 to 120 days	120 days (never done before)
2. Hybrid System	YES	YES	YES	YES
3. Interactive Simulator	YES	YES	YES	YES
4. Short Protected Drivers	Programable (to +20 Volts)	Programable (to +15 Volts)	Programable (to +30 Volts)	Programable (+17 Volts)
5. Capable of Programming Time share machine (no & Testing at same time testing limitation)	YES	YES	YES	YES
6. Software Backup support	YES	YES	YES	YES
7. Proven Capability	a) Started 1968 on PC Card testing-not similar at all b) Hardware in 1974; now simulator early 1975 between 6 to 10 systems	a) Hardware in Nov 72 w/o Simulation (60 Systems) b) Only one customer with latest simulation software.	a) Tester 1970, First Caps Simulation available in 1972 b) Started in 1974. Approx. 80 in field	a) Building custom for approx. 5 years (approx. 100) b) Building since 1975; Simulator Software on between 5 to 10 systems.
OTHER BASIC CRITERIA				
1. Cost:	\$236.4K	\$310.4K	\$292.2K	\$312.9K
2. Analog Capability Level of Measurement DC	Observed .1MV reading capability. Zehntel hardware Switching Matrix (3X200) ? Accuracy	Observed .3MV reading No specs on system Fluke 8375 + Matrix (8X16) accurate to 1.5volts expected system 2MV	Observed .8MV reading & accuracy of 1MV. Stated accuracy $\pm(0.25\%$ of reading $\pm(0.25\%$ of FS) 200MV $\pm(0.25\%$ of reading $\pm.05\%$ Expected System 5MV	Expected system 5MV accuracy Commerical equipment -FLUKE 8375
Freq. Meas.	10 Meg HZ limit Dana 8015	1 Meg HZ limit HP 5326	10 Meg HZ limit	3.5 Meg HZ limit HP 5326
Threshold Det.	Not Available	Not Available	1% Capability	Not Available
A.C. Measurement	0.1 to 1000 Volts AC	Not Included	15MV to 150 Volts AC	Not Included
D.C. Stimulus AC Stimulus	Resolution 1MV(0 to 10M) W/Tech 154	Resolution 1MV(0 to 10MD) W/Tech 154	Resolution 5MV(0 to 10V) W/Tech 154	Resolution 1MV HP6130 + 1 W/Tech 154
3. Programming Data Entry	Keyboard or Card Network description Can fault path-very good	Cards or Keyboard Network Description Special node identif. Track back by node no.	Keyboard or Papertape Network description Nomenclature of schematic Manual using schematic All but Hyperbolic	Keyboard or Card Reader Network description Nomenclature of schematic Manual tracking with schematic Arithmetic and logic functions
Node Verific. Arithmetic Capab. Model Library Simulation Basis	No Basic Gate + manual generated functions-zero delay	No Macro functions+primary elements	Basic gates & special machine language unit de-lay 74XX	Basic gates + micro functions actual gate delay

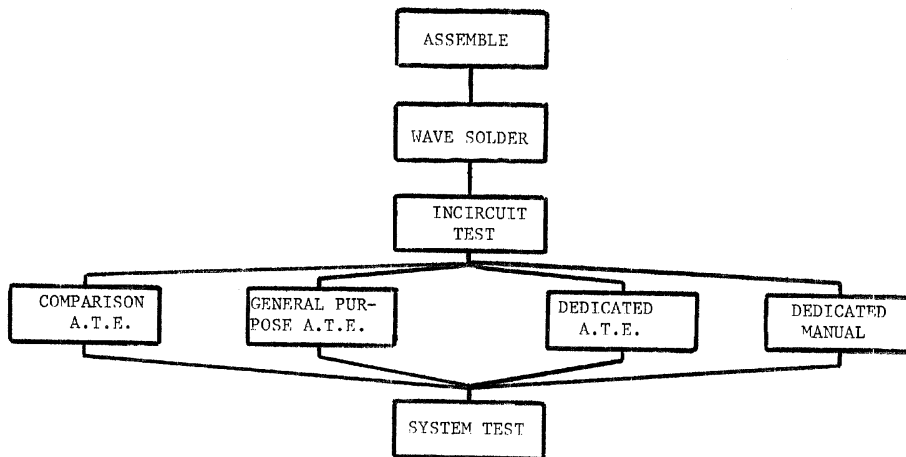
OTHER BASIC CRITERIA							
Model Library(Cont'd)	A	B	C	D			
Edit Capability	No commitment or library expansion charges after 1 yr.	Each new special chip is \$500 each; anything in T.L. book is covered	series modeled; all other most likely have to be modeled at cost.	Approx. 200 elements;automatic update @ no cost except for custom chips.			
Fault Verification	Line Run time 7 + hrs for 20 I.C. Bds.	Line Run time 11 + hrs for 20 I.C. Bds.	Character (CRT pg memory) Run time; 1 hr for 20 I.C. Bds.Differentiation between pin to pin and ground shorts	Character Run time; 1 hr for 20 I.C. Bds. Same as C.			
Data Transfer from prgming to test Keyboard Manipulat.	On same machine; no transfer required.	1 transfer on cassette disc.	Transfer disc.	Transfer to disc.			
4.Ease of Maintenance	Largest effort Self test for machine,some board testing procedures spares package recommended, no problem foreseen.	Moderate effort Self test for machine, spares package recommended.Potential cassette problem with wired backplane.	Acceptable effort Self test for machine; commercial stim. Spares recommended.Calibration must be done at machine.	Minimum effort Remote diagnostics (modern) commerical stim & monitor spares recommended.			
5.Warranty	90 days all; one year all "A" built parts. \$32/hr. & Transportation(from Cal.)	90 days all; one year on "B" parts(Tech. available from Texas)	90 days all; one year on all GR parts - \$35/hr & Transportation(tech from NJ).	90 days all; one year on all I.E. parts. tech from available.			
6.UUT Interface	Virginia panel type	Spring loaded blade to a P.C.B.	50 pin connector	Virginia Panel			
7.Computer & Memory	General Automation SPC-16/40; 32K; 16 bit	960 I.T.: 65K; 16 bit	PDP 8E; 15K; 12 bit	Intra Date 7/32; 24K; 32 bit			
8.Diagnostics	Single point digital probe(look ahead)	Dip Clip (output back)	Single point probe (look ahead)capability to determine shorts to ground; VCC or pin to pin ground.	Dip Clip (Output back) look ahead coming in future.Capability to determine shorts to ground. VCC, pin to pin & pulse detection.			

ATTACHMENT II

K-T ANALYSIS OF A.T.E.
FOR
HONEYWELL FT. WASHINGTON, PA.VENDORS

	WEIGHT	A		B		C		D	
		REL	EXT	REL	EXT	REL	EXT	REL	EXT
COST	6	7	42	4	24	5	30	2	12
ANALOG DC MEAS.	8	6	48	7	56	4	32	4	32
ANALOG AC MEAS.	4	8	32	4	16	6	24	5	20
ANALOG STIMULUS	7	6	42	6	42	3	21	5	35
NODAL ACTIVITY	7	9	63	4	28	6	42	4	28
MODELING & SIMULATION	9	3	27	8	72	5	45	9	81
EDIT CAPABILITY	5	4	20	4	20	8	40	9	45
FAULT VERIFICATION	6	2	12	3	18	8	48	7	42
EASE OF MAINTENANCE	8	5	40	2	16	4	32	6	48
WARRANTY	2	2	4	3	6	5	10	4	8
UUT INTERFACE	4	4	16	5	20	6	24	4	16
COMPUTER & MEMORY	3	5	15	6	18	3	9	8	24
DIAGNOSTICS	8	5	40	8	64	6	48	7	56
PROVEN CAPABILITY	10	3	30	7	70	9	90	2	20
TOTALS			431		470		495		467

ATTACHMENT III



CALIBRATION SUPPORT FOR NUCLEAR POWER STATIONS

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INTRODUCTION

Measurement support for Nuclear Power Stations is an economic and engineering necessity. Adequate calibration control assures that measurement of plant processes are valid, accurate and within acceptable limits. To fulfill this need, Duke Power Company maintains a centralized standards laboratory which assures that company measuring and test equipment is accurate and based on either lawfully established units of measurement or physical constants of nature. Four nuclear stations are currently serviced by the laboratory: Oconee Nuclear Station (which is in operation), McGuire Nuclear Station, Catawba Nuclear Station, and Cherokee Nuclear Station consisting of 10 nuclear reactor units all located in North and South Carolina.

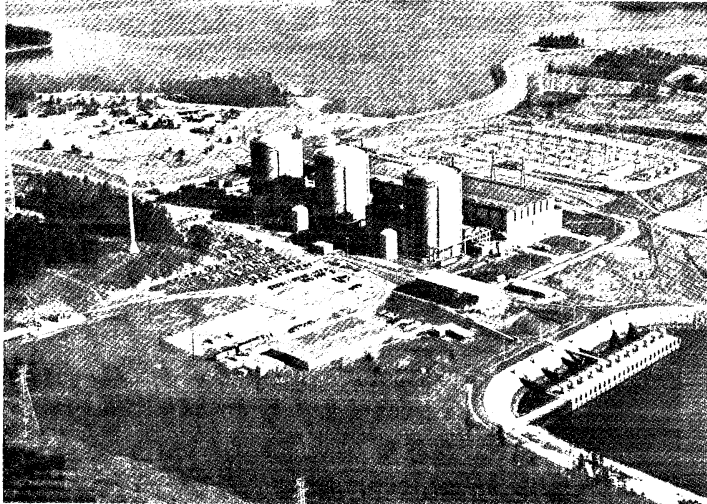


FIGURE 1 Oconee Nuclear Station

CALIBRATION ECONOMICS

Economic operation of power generating units is a necessity to meet company objectives of providing reliable power at the lowest practical cost to the consumer. Why, then, are calibrations and standards considered such an important area? Similarly stated, calibration errors can cost money.

Duke Power Company now has three pressurized water reactors in operation at Oconee Nuclear Station in South Carolina. Each unit is capable of supplying 886 Mw of electrical energy. A primary consideration for efficient operation is the control of steam pressure and temperature at the turbine throttle. Typical increased operating cost for Oconee Nuclear Station, based on a 1% loss in throttle steam temperature and pressure, is illustrated as follows:

- (a) 1°F loss in throttle steam temperature from optimum results in \$48,000/year higher generating cost (3 units)

- (b) 9 PSIA loss in throttle steam pressure from optimum results in \$115,200/year higher generating cost (3 units)

Type "J" (iron constantan) thermocouples are utilized to monitor temperature of throttle steam. Normally, such thermocouples have calibration uncertainties of 2°F . Accuracy of the thermocouple, discounting calibration uncertainty, can approach 5°F . The addition of reference junctions, thermocouple extension wires and selector switches can introduce another $\pm 6.5^{\circ}\text{F}$ of error. These figures result in a worst case condition of $\pm 13.5^{\circ}\text{F}$ uncertainty when utilizing normal state of the art measuring equipment. Steps can and are taken to minimize this figure. However, thermocouple output does change with time. Often uncalibrated thermocouples can have errors considerably larger than those noted. Therefore, recalibration and comparison to known temperatures can and must be accomplished at regular and periodic intervals in order to reduce the measurement uncertainties and subsequent higher generating cost.

Pressure transmitters are utilized to monitor throttle steam pressure and are usually accurate to $\pm 1/2\%$. On recalibration, some transmitters have been known to have errors in excess of 1% of full span or range (120 PSIA). These figures are considerably larger than the 9 PSIA figure previously mentioned. Errors of this magnitude must be reduced to acceptable limits. Again periodic recalibration is a must; however, it should be realized that no measurement is perfect. State of the art limitations in science and technology limit the accuracy of many measurements and control processes.

Bearing failure can cost considerably more than replacement of bearings before failure. Normal maintenance before failure might require one or two days while a failure repair on the same equipment might keep a unit out of service for several weeks. Therefore, valid engineering decisions must be made based on accurate measurements. These decisions are often based solely on instrument measurements such as bearing temperature. If a thermocouple erroneously indicates excessive bearing temperature, a unit may be shut down prematurely with the subsequent reduction in system capability, unit availability, and increased operating cost. Conversely, a thermocouple or resistance thermometer which indicates a satisfactory temperature, when in fact the temperature is excessive, might lead to major damage to equipment and inability to meet the consumers demand for electricity. Calibration gives the accuracy and assurance necessary for valid engineering judgement in these circumstances.



FIGURE 2 Standards Laboratory Electrical Calibration Area

REGULATION

Nuclear Power Plants, of course, operate within the framework of many regulations and under the inspection of regulatory authorities. Title 10 Code of Federal Regulations, 10CFR50 Appendix B, establishes the Quality Assurance criteria for Nuclear

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

Duke Power has developed a centralized standards laboratory which fully implements this regulation and provides the necessary support to nuclear stations in the following measurement areas:

- length
- flow
- temperature
- pressure
- electrical measurements (resistance, voltage, current...)
- acceleration
- mass
- rotational
- humidity

Several thousand instruments, gages, and test equipment can be found at each nuclear reactor unit. Figure 3 illustrates the massive number of instruments found solely in the control room. Each instrument/display is fed by one or more sensors, all needing calibration.

Other criteria that may be imposed in addition to the above, depending on the type of reactor include the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section III, ANSI N45.2-1971 or RDT-F-3-2.

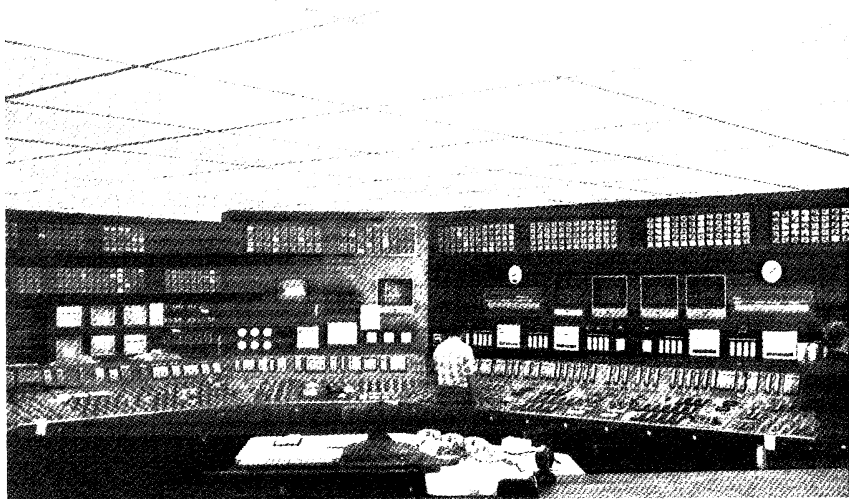


FIGURE 3 Nuclear Reactor Control Room

CALIBRATION CONTROL

A calibration system specification details in writing what measures have been implemented to control the calibration process. In addition to a system description, written calibration procedures are a necessity. The calibration specification utilized by Duke Power Company encompasses each of the following areas:

- Calibration Procedures
- Calibration Records
- Recall System
- Calibration Intervals
- Instrument Identification

- Status Labeling
- Environmental Controls
- Calibration Service Procurement
- Traceability
- Nonconforming Instrument Control
- Audits
- Personnel Training
- Accuracy Ratio
- Standard to Test Instrument

Procedures

Written procedures are required for all activities affecting quality and are developed prior to instrument calibration. Procedures are either developed internally or when possibly extracted from the government industry data exchange microfilm data bank. After review and approval, these procedures are issued as controlled documents. Procedures that are developed are written to conform with the National Conference of Standards Laboratories recommended guide. Quantitative and qualitative acceptance criteria is included in the text of the procedure for each instrument.

Records

A master history file for each item of measuring and test equipment is generated and stored for as long as the station operates or the life of the instrument whichever is greater. The equipment history contains:

- instrument identification number
- name of instrument manufacturer
- model number
- manufacturer serial number
- equipment description
- calibration interval
- purchase date
- calibration history
- specialized remarks
- calibration data (as found and as left)
- out of tolerance notices
- calibration status

Each instrument is assigned a unique identification number consisting of ten alphanumeric characters. The first five characters identify the nuclear station and group responsible for the instrument. This is the instrument master number and all records are keyed to this identifier.

Traceability

Each instrument calibrated must have its calibration genealogy traceable through serialization of the instrument and documentation of this serial number on the calibration report, to a nationally recognized standard. This can be accomplished by directly returning certain standards to the National Bureau of Standards (NBS) or by having suppliers calibrate the standards with instruments calibrated by or traceable to NBS. Often return of the instrument to an outside agency takes a considerable amount of time. This demands increases in the inventory of measuring and test equipment to assure continued operations.

If possible, one way of minimizing this extra inventory and reducing cost is to provide calibrations based on natural physical constants. This calibration method is accomplished by utilizing light waves as a standard of length and melting points of selected metals and the triple point of water for temperature. A great deal of the measurement uncertainty associated with transfer measurements of the comparison type can be eliminated and more accurate measurements realized when using natural physical constants. However, at some time during the calibration cycle, comparative transfers must be accomplished. The standard is maintained at four times the accuracy requirement of the measuring and test equipment calibrated. This results in the so-called "4 to 1" rule which reduces the uncertainty associated with the calibration process. State of the art technology often precludes the maintenance of this "4 to 1" rule with a resulting decrease in accuracy.

Mathematical and statistical methods are employed which result in a scientific analysis of error uncertainty associated with the calibration process when this "4 to 1" rule is not achievable or infeasible. Carefully planned experimental procedures and repeated measurements result in adequate control when limitations on accuracy are encountered.

COMPUTER DATA BASE

A computer data base is maintained which stores a current history of the instrument via a Cathode Ray Tube (CRT) terminal which is linked to an IBM 370-165 computer system. This terminal is used to access and update this computer data base both at the laboratory and at the generating stations. While the program is an invaluable aid and provides for efficient management of several thousand instruments, it is not a quality assurance requirement.

The equipment history data base contains data such as:

- identification number
- model number
- manufacturer
- equipment name
- calibration interval
- serial numbers of instruments used to calibrate the instrument
- calibration date
- calibration status
- calibration due date
- calibration schedule date

Traceability is assured by the entry of the identification number of the test standard into the data bank. The computer checks to assure that the standard used for the calibration has a current calibration status traceable to the National Bureau of Standards by scanning the data bank. If the standard used does not have a valid status, the computer changes the instrument entered to a "REJECT" status. Standards discovered to be in error can cause a bookkeeping problem since the effect of out-of-tolerance conditions on prior calibrations must be evaluated. A cross reference program can be initiated that will list all instruments calibrated by the non-conforming standard since its last valid calibration.

Recall of instruments occurs automatically as the computer generates a daily list of all instruments that have exceeded their specified calibration interval. The computer changes the status to "out-of-calibration" in the data base. Additionally, an Instrument Management Program is generated weekly listing a summary of each instrument's status as illustrated in Figure 4.

SUMMARY

Efficient and reliable operation of nuclear power stations is a must. Calibration provides one mechanism to support this effort. Accurate measurements lead to valid decisions. Calibration error may be causing increased generating cost and inefficiency. Industry standards and regulatory requirements demand calibration to assure the efficient and reliable operation of power reactors. Measurement control systems, as described, allow for accurate engineering assessment of test and operating data to assure efficient and reliable operation of nuclear power plants to supply our customers demand for energy.

REFERENCES

1. Benedict, R. P., Fundamentals of Temperature, Pressure, and Flow Measurements (John Wiley and Sons, New York, 1969), pp. 67-75.
2. ASTM Special Technical Publication 470, Manual on the Use of Thermocouples in Temperature Measurement (ASTM, Philadelphia, 1973), p. 11.
3. Code of Federal Regulations, Part 10, Energy (U. S. Government Printing Office, Washington, 1977).
4. Harrison, M. J. and Adams, C. A., System Instrument Management Program Users Manual Duke Power Company, 1977. (Unpublished)

DUKE POWER COMPANY - STEAM PRODUCTION DEPARTMENT
INSTRUMENT MANAGEMENT REPORT
77/12/20

SYSTEM ID	PLANT ID	SERIAL #	MODEL #	NAME	CLASS	LOC	LAST CAL	CAL DUE	SCHEM CAL	YEL	STATUS
SVIAC11510	NONE	UP-1	S436ERL	STJ	MICROMTR+00	HK				12	NPC
SVIAC11511	NONE	DP-1	S436ERL	STJ	MICROMTR+00	HK				12	NPC
SVIAC11512	NONE	DP-1	S436ERL	STJ	MICROMTR+00	HK				12	NPC
SVPR11701		1782958	8493-2	LEA	POTOMTS TEMP	SL	77/04/14	78/09/14	78/09/12	12	IN CAL
SVPR11703		22640	DR64000	PUD	DIGICAGE APS	SL				12	NPC
SVPR11704		22648	DR64000	PUD	DIGICAGE APS	SL				12	NPC
SVPR11705		22647	DR64000	PUD	DIGICAGE APS	SL				12	NPC
SVPR11706		160386 & 866	PRI-4024	EDG	FLOWMETER	SL	76/11/09	76/11/09	76/11/07	12	OUT CAL
SVPR11707		1782717	8492-2	LEA	POTOMTS TEMP	SL	77/11/07	78/11/07	78/11/07	12	IN CAL
SVPR11708	SY	107817	12-00444	PAC	FLOW METER	SY				12	NPC
SVPR11709	TEMP POT	1782957	8493-2	LEA	POTOMTS TEMP	SY	77/02/25	78/02/25	78/02/22	12	IN CAL
SVPR11710		1907800	8593-2	STJ	MICROMTR+00	SY	77/06/19	77/11/19	77/11/17	06	OUT CAL
SVPR11711		1782739	8593-2	LEA	POTOMTS TEMP	SY	77/11/07	78/11/07	78/11/07	12	IN CAL
SVPR11712		1807707	8602-2	LEA	POTOMTS TEMP	SY	77/11/07	78/11/07	78/11/07	12	IN CAL
SVPR11713	NONE	NONE	NONE	DPW	THERMOCOUPLES	SY	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11714	NONE	NONE	NONE	DPW	THERMOCOUPLES	SY	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11715	NONE	NONE	NONE	DPW	THERMOCOUPLES	SY	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11716	NONE	NONE	NONE	DPW	THERMOCOUPLES	SY	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11717	NONE	NONE	NONE	DPW	THERMOCOUPLES	SY	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11718	NONE	NONE	NONE	DPW	THERMOCOUPLES	SY	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11719	TRAINING CEN	4264074	475	TEA	OSCOPE	TC	77/10/10	78/10/10	78/10/10	12	IN CAL
SVPR11720	TRAINING CEN	32050	85004	ELA	MTR DMM	TC	77/01/01	77/01/01	77/01/01	04	OUT CAL

FIGURE 4 Instrument Management Report Weekly Printout

SYSTEMATIC MEASUREMENT ERRORS

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I. INTRODUCTION

Statistical analysis of measurement errors has become an additional tool metrologists are using in an increasing number of applications and at an increasing rate in order to determine numerically the accuracy of measurements and the confidence attached to quoted accuracies. Methods of evaluating random errors are well known and in widespread use. This paper examines the main aspects of systematic errors and methods to evaluate them; it discusses the nature of the fluctuating boundaries between systematic and random errors in measurements and calibrations.

The systematic error of a measurement or calibration may be defined as the largest possible estimated difference between the true value of a measured quantity and the mean value towards which the measurement or calibration process tended as a limit at the time of the measurement and which difference could not be eliminated for technical or economic reasons; it is an estimate of the maximum limits of the effects of all error sources known or suspected to exist which tended to offset uniformly all results of repeated applications of the same measuring or calibration process at the time of the measurement. Thus, the "systematic error" is not an error in the accepted sense of the word "error", but rather an uncertainty; however, the term "error" will be used here for brevity and because it has been firmly established by custom.

II. TYPES OF MEASUREMENT ERRORS

A. General

The error or uncertainty of a measurement can be divided into a fixed part and a variable part, where it should be understood that the fixed part remains approximately fixed only for the duration of the measurement process. For shorter durations, the variable part is likely to be smaller, and over longer time intervals, the phenomena causing the "fixed" error can be expected to vary also, thus making the variable part of the error larger at the expense of the "fixed" part. As the time interval under consideration becomes very large, any initially fixed error will probably vanish and all errors are likely to become variable.

The errors or uncertainties of a measurement can also be categorized by a random part and a systematic part. The random error is part of, but not necessarily identical with, the variable error; and the systematic error includes the fixed error, but may also include a portion of the variable part of the error.

All determinable errors which occur during one measurement process and which do not appear* to be part of the random error must be accounted for, otherwise the process may not be under statistical control. But "... until a measurement operation ... has attained a state of statistical control it cannot be regarded in any logical sense as measuring anything at all."⁽⁴⁾ Capability of control means that either the measurements are the product of an identifiable statistical universe or an orderly array of such universes, or if not, the physical causes preventing such identification may themselves be identified and, if desired, isolated and suppressed."⁽¹⁾

B. Systematic Errors

A systematic error is that value which, when added to, or subtracted from, the limiting mean value of a measurement process of a quantity, produces a range in which the "true value" of that quantity is believed to lie. We hope that the systematic error is always equal to or larger than the difference between the "true value" of the quantity and that value toward which the measuring process of the quantity tends, this tendency not being caused by chance fluctuations of any part of the measurement system.

The systematic error is a bias, but generally unknown in magnitude and direction, because the "true value" is an abstract concept which cannot be physically realized. More pragmatically

*The word "appear" is used, "... because, as is always the case in trying to find a law controlling a phenomenon, we can never be sure that we have discovered the law. Obviously such appearance is not sufficient in the logical sense although it must be in the practical sense."⁽¹¹⁾

"... the systematic error ... of a measuring process refers to its tendency to measure something other than what was intended. . . . On first thought, the 'true value' of the magnitude of a particular quantity appears to be a simple straightforward concept. On careful analysis, however, it becomes evident that the 'true value' of the magnitude of a quantity is intimately linked to the purposes for which knowledge of the magnitude of this quantity is needed, and cannot, in the final analysis, be meaningfully and usefully defined in isolation from these needs." (4)

A systematic error is always an estimate of a range, and estimating it requires a profound understanding of the measurement process if a realistic figure is to be arrived at. A quoted figure for the estimate of a systematic error means that the metrologist believes that he would have detected – and, therefore, been in a position to reduce – any error larger than that quoted as the systematic error. It implies that the actual, unknown error could be anywhere within that range. And "... the wiser and more careful the experimenter's search for systematic errors, and the more completely he has eliminated them, the less likely is it to lie near the limits of the range." (3)

Dorsey (3) describes the concept of the systematic error as being "... used to cover all those errors which cannot be regarded as fortuitous, as partaking of the nature of chance. They are characteristics of the system involved in the work; they may arise from errors in theory or in standards, from imperfections in the apparatus or in the observer, from false assumptions, etc. . . . They are frequently called 'constant errors,' and very often they are constant throughout a given set of determinations, but such constancy need not obtain . . .

"In searching for systematic errors, the logical procedure is to make a series of measurements, then to change something and to make another series, and to compare the means of the two groups. This will be repeated as often as may seem necessary.

"In the absence of such a search, the worker can do no more than hope that all is going well. The fact that he sees no reason for suspecting the presence of an unknown systematic error is of no importance at all, no matter who the observer is. The really troublesome errors are exactly those that are not suspected. The expected ones can usually be to some extent eliminated." (3)

Sometimes economics dictate the use of a coarse measurement system whose major component of systematic error can be determined by comparison with a more accurate measurement system. This component can then sometimes be accounted for by a correction. The remaining systematic error will thereby be reduced; it may even become negligibly small, but it will theoretically never become zero. However, the systematic error of the coarser system may vary, and it may not be practical to determine it each time a measurement is to be made. In this case, no correction may be applicable, and the comparison with a more accurate system may only serve to estimate the range of the systematic error of the coarser system more accurately than would be possible without recourse to a more accurate system. This is the case, for instance, with a working instrument with a rated accuracy or uncertainty of 1% routinely calibrated by working standards with 0.1% uncertainty limits. The 1% uncertainty of the working instrument is its systematic error contribution to all measurements made with it, unless corrections are provided, in which case the systematic error may be less. The calibration against the standards then serves to assure that this systematic error does not exceed 1%.

III. THE CHANGING NATURE OF ERRORS

The boundaries between systematic and random errors are fluctuating. What appears as a systematic error under one set of circumstances may appear as a random error under another and vice versa, just as a sculpture changes its appearance to a viewer walking around it. The consequences of this fact, as they affect the evaluation of uncertainties of standards in a laboratory, are illustrated by a few examples.

A. A Random Error Becoming Systematic Error

When a standards laboratory A, say the National Bureau of Standards, calibrates a reference standard for us, laboratory A reports to us the value of the standard, as it has determined it by its measurements, and the limits of uncertainty of that measured value. Part of laboratory A's uncertainty originates from its random error, part from its systematic error. Random error and part of the systematic error can be expected to add a small variable component to laboratory A's measured value in such a way that each time laboratory A measures the standard, the resulting measured values will differ slightly from the ones obtained earlier or later. However, once a value and its limits of uncertainty are reported to us, they are fixed, no more variable, least of all "random variables", and the entire uncertainty, including random error, must be considered by us as a systematic error when we need to apply it. The necessity of the foregoing was discussed in detail by Youden in Reference 12. (See also Ref. 10.)

In Part III.B., under "varying Systematic Errors of Standards", we shall see how trend charts can help us "unfreeze" the random error and the variable part of the systematic error of laboratory A in the long run to reduce the total uncertainty accompanying the value of our standard. But without such techniques, the total uncertainty of a higher echelon measurement becomes a systematic error in its lower echelon application. (See also Reference 15.)

B. Varying Systematic Errors of Standards

The certification uncertainty of our standard is not the only uncertainty introduced by the standard. In general, another uncertainty term must be found which combines all those fluctuations in the value it represents as may be caused by changes in the standard itself, usually due to drift, instability, or use (wear), or by external influences which temporarily affect the value of the standard, such as temperature, barometric pressure, air ionization, solar activity, etc., and which are not controlled – and may not even be known to have an effect – at the time the value of the standard is being determined. Some of these effects may at least partly be accounted for in the random error of the measurement process employed when determining the value of the standard. But, unlike that part of the random error which is entirely caused by the measuring process and the effect of which will remain constant once the measuring process is terminated and the value of the standard reported, the latter effect will continue to change the value of the standard, adding to the uncertainty.

In general, we would not know whether differences in subsequent values of our standard as certified by Laboratory A are caused by the random error of Laboratory A only, by changes in Laboratory A's systematic error, by changes in the value of the standard itself, or by a combination of these causes. To be able to assign to a standard an uncertainty which includes all experienced effects of variation from the unknown and unknowable true value of the standard, we must analyze the history of that standard.

A valuable tool in analyzing and displaying the history of a standard is a Trend Chart (see Figures 1 and 2). The dots and x's on the Trend Charts represent values reported by the National Bureau of Standards (NBS) for the standards in question at the indicated dates. Their dispersion pattern suggests a Trend Line which represents the best value known of each standard. The Trend Line value of the standard is most likely a more accurate value of the standard than the latest NBS reported value, and the Trend Chart has on occasion served to correct errors in the NBS reported values. The dispersion of the points shows graphically the effect of all the variables influencing the known value of the standard over the long run, such as possible long term variations in the systematic error of the standardizing Laboratory (NBS in this case), its random error, and actual changes of the standard. In fact, the Trend Charts of the gage block indicated a shrinkage of the block before the reasons for such shrinkage were known (wear effects could be excluded in the case of the block represented by Figure 2).

Furthermore, the calculated envelope around the points at two or three sigma of the points' dispersion around the Trend Line represents the total uncertainty of the value of the standard, excluding the systematic error of the standardizing laboratory. The systematic error of the standardizing laboratory is possibly in part included in a Trend Chart spanning a long period, but we don't know how much of it is included, if anything. Thus, to estimate the total uncertainty of the standard's value at any time, we must add the reported systematic error of the standardizing laboratory to the width of the envelope on the Trend Chart. And this total uncertainty of the standard is part of our systematic error when we use the standard as a basis for measurements. Note that this systematic error includes random variables which have been frozen for the time being and must be considered as being part of the systematic error.

For a detailed description on how to construct Trend Charts, see References 8* and 9.

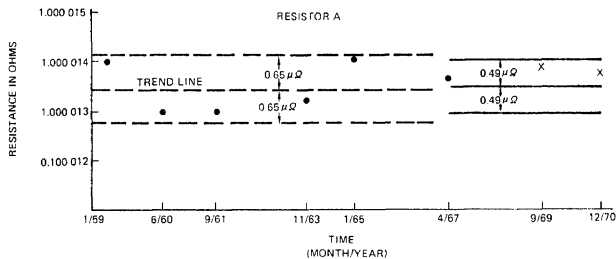


Figure 1. Trend Chart of a Thomas Type Standard Resistor

*Reference 8 should only be used with an errata sheet available from the author since it contains numerous typographical errors.

Figure 1 shows the Trend Chart of a standard resistor constructed in January 1965 (dashed lines). At that time, the best value for this resistor was 1.000 01344 ohms (Trend Line). In the absence of any information to the contrary, the Trend Line was believed to be horizontal, assuming no detectable change in the value of this resistor for the near future (two to three years).

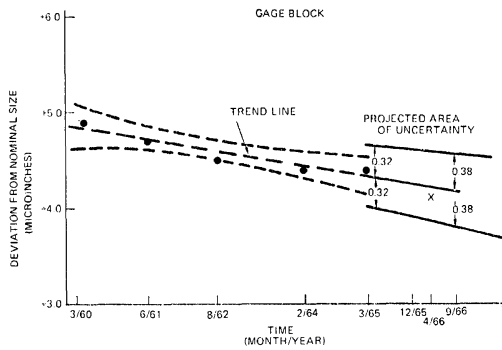


Figure 2. Trend Chart of a Gage Block

Because of the scarcity of the points available, 2-sigma control limits were drawn based on the scatter of the points around their average (the Trend Line in this case); this gives a 95 percent confidence that the "true value" (i.e. the limiting mean value of all experienced variables) lies between those control limits, disregarding for the moment any systematic error of NBS. As more points become available 3-sigma control limits would reduce the risk of the limiting mean value being outside the control limits to an insignificant 0.3 percent.

As the Trend Line value of this standard is the best known value, this is the value assigned to the resistor at any time, regardless of the latest calibration value of the resistor reported to us by

NBS. Note that the reported values have been jumping up or down by as much as one part per million from one calibration to the next. If we would always assign the latest calibration value to these standards, our entire measurement system would experience these ripples, ripples which in the end would cancel each other around the limiting mean value, the Trend Line value. Instead, we compute a new Trend Line value, a new mean value in this case, every time a new calibration value is obtained. Thus, every new calibration value will change the new mean only insignificantly, if at all. Hence the Trend Line value assigned to the standard will remain stable over the years.

The control limits represent the limits of uncertainty of the Trend Line value and hence, represent the limits of uncertainty due to variable error components of the value which we assign to the standard. They encompass many more variables and sources of uncertainty than those experienced by NBS in the calibration of the standards. The limits of uncertainty about the Trend Line of the first five values of Resistor A, Figure 1, are at 0.65 microohms from the Trend Line; adding to that the estimated limits of the systematic error by NBS of about 0.5 microohms, the total uncertainty of the value of Resistor A (1.000 013 44 ohms) is 1.15 microohms. This is the systematic error introduced by the standard to any measurement made with it. Note that the 0.65 microohm control limits represent a 95 percent confidence that this range brackets the "true value" of the standard. If we want to increase the confidence limits to 99.73 percent (3-sigma equivalent), the control limits would have to be widened to 1.53 microohms about the Trend Line value for a total uncertainty of $1.53 + 0.5 = 2.03$ microohms. In order to narrow these limits of uncertainty, we need a longer history with more values.

Many a laboratory is using the latest calibration value of their standard as the value assigned to it until the next calibration of that standard and use the uncertainty reported by the calibrating laboratory (NBS in our case) as the total uncertainty of the standard's value. The fallacy of that practice becomes evident from the above discussion. These laboratories in fact experience a far higher uncertainty than they are aware of.

Figure 2 shows a Trend Chart of a special gage block to illustrate the fact that some standards undergo gradual changes in time. In such cases, a Least Squares Trend Line can be constructed, depicting with sufficient accuracy the behavior of the standard and permitting a forecast of its most likely value for the near future. Since the slope of such a Least Squares line is also burdened with some uncertainty, the band of uncertainty around the forecast future values of such standards continues to widen as time progresses as shown in Figure 2, expressing numerically our uncertainty about the exact value of the slope. This widening bandwidth of uncertainty also tells us when we need to have the standard recalibrated, lest its uncertainty grows intolerably large for the requirements of our products.

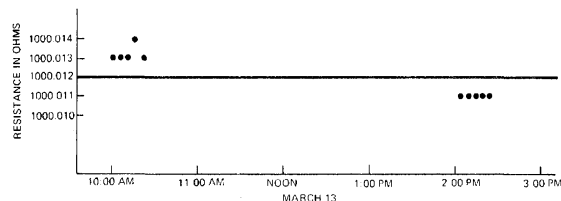
The dots represent the values known at the time at which the Trend Charts were constructed and on which the Trend Charts are based. The x represents a value obtained later, and is shown to illustrate the predictive value of the Trend Chart. The Trend Charts are, of course, updated each time a new value is obtained, as exemplified by the solid lines in Figure 1.

C. Varying Systematic Errors of Measurements

The magnitude of a systematic error of a measurement process is established by the capability and willingness of the metrologist to measure those phenomena which cause systematic errors, to find their quantitative effects (i.e. what quantity of the phenomenon is required to cause a measurement error of a given magnitude), and to account for them or eliminate them.

If it is known how much of a phenomenon causes a given amount of a measurement error and if we are capable – technically and economically – of measuring the phenomenon and making the required adjustment, the systematic error is determinable and should be eliminated. If the state of the technology or economics forbid a determination and subsequent elimination of the systematic error, it remains unknown and must be estimated. The following example is intended to illustrate the transitory nature of the limits between systematic and random errors of a measurement process.

An unknown standard resistor with a nominal value of 1000 ohms was compared against a known standard resistor one day between 10:00 a.m. and 10:20 a.m. A ratio set was used for comparing the two resistors in air. The five values obtained were plotted on a chart, Figure 3. The ambient temperature was 25.4 degrees Celsius, varying by less than 0.1 degree during that



time. The temperature coefficients of resistance of the two resistors were known, and all plotted values were corrected for a base temperature of 25 degrees Celsius.

The effect of temperature on the entire measuring system was not known. The ambient temperature varied between approximately 25.5 and 24.5 degrees C

Figure 3. Two Sets of Measurements of a 1000-ohm Standard Resistor

at a typical rate of approximately 0.5 degrees C per hour. It could, therefore, be assumed that the system was not at thermal equilibrium at any time; and the effect of this inequilibrium on the result of a single set of measurements would have to be estimated and a numerical value assigned to this effect as part of the systematic error if the value of the unknown resistor had to be determined on the basis of the first set of measurements. The nearly perfect agreement of the values obtained in the first set indicates that the resolution of the ratio set was insufficient for the measuring system to respond significantly to random fluctuations. An analysis of the random error of this set based on more than an inspection of the data, where four values are identical and only one differs from the other four by the smallest unit possible to resolve, would be of little value.

The correct value of the standard resistor had been determined by a more accurate measurement process before and after the measurements described in this example and was 1000.0120 ohms with a constant systematic error and with a random error of considerably less than 1 ppm.

Between 2:00 and 3:00 p.m. of the same day, another set of measurements was made and is also plotted on the control chart. The ambient temperature was 24.9 degrees Celsius. Again, the five measured values, corrected for the base temperature, agreed very well; perfectly, as a matter of fact. But they differed markedly from those obtained previously. It could be said that each set of measurements was under (simple) statistical control individually; but both sets together indicate an out-of-control condition, the two sets being offset from one another by a systematic error. Since no means were available to keep the ambient temperature more stable, and since the effect of temperature inequilibrium on the components of the measuring system was not known, this systematic error is unknown. If it had been possible to predict the systematic error due to temperature difference and inequilibrium or to maintain the ambient temperature more closely, the measured values could have been adjusted for the temperature inequilibrium, or the condition causing the inequilibrium could have been avoided. (The effect of temperature on the systematic error of the resistance measurement is given here as one example only. Many other sources of systematic error exist in practice and may influence the measurement uncertainty.)

The resistance of the unknown standard resistor was then measured repeatedly under similar circumstances. The results of these measurements were entered on the chart shown in Figure 4. Each plotted point is the mean of five successive determinations of the resistance of the unknown corrected, as far as possible, for 25 degrees Celsius. The points now are randomly distributed about a mean of 1000.0124 ohms. Whereas each group of five resistance determinations was made with a very small random error and an appreciable systematic error, the new mean has a drastically reduced systematic error, but an appreciable random error. By

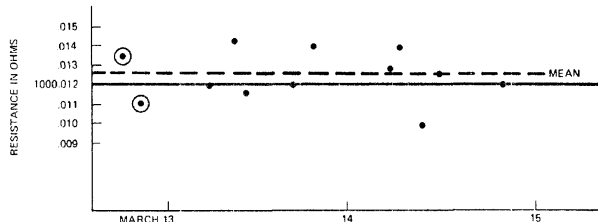


Figure 4. Twelve Means of Sets of Five Measurements

⊙ Averages of values from Figure 4.

in terms of the new cause system and process, vary in a random fashion and therefore be attributable now only partly, if at all, to bias. Furthermore, enlargement of the cause system requires re-evaluation not only of the bias involved in the stated accuracy but also of the stated precision."

Temperature changes, like many other causes of systematic errors, frequently occur in patterns, such as rough sinusoids or, in the case of closely controlled environments, in sawtooth patterns, not randomly. The random appearance of the points on the chart of Figure 4 is due to the random selection of the times at which the measurements were made. It is interesting to note that an overestimate of the limits of uncertainty due to random errors would be obtained if the points would follow exactly a sinusoidal or a sawtooth pattern and the calculations were made as if they were normally distributed. In fact, all points of a sinusoid are within a region bounded by $0 \pm \sqrt{2}\sigma$ or within 1.41 standard deviations from the mean, and all points of a sawtooth curve of isosceles triangles with height h are within a region bounded by

$$\frac{h}{2} \pm \sqrt{3}\sigma$$

or within 1.73 standard deviations from the mean.

The preceding examples illustrate, therefore, that:

1. A measuring process ordinarily under statistical control will get out of control if the systematic error of the process varies, but control may be reestablished if enough changes are allowed to occur and the changes in systematic error are allowed to join the chance system of variations.
2. If changes in systematic error are allowed to occur, the standard deviation of the measuring process will be larger than in the absence of such changes, and the systematic error will be reduced.
3. The time element will probably always change the "cause system" and transform constant errors to changing errors, and parts of systematic errors into random errors.

The last example, however, raises another question. Is the 0.4-milliohm difference between the mean and the certified value attributable to a systematic error or could it be caused entirely by the fluctuations which a mean from a limited number of measurements could be expected to display? Is there, in other words, a bias in the measuring process which should be eliminated? Section V will show one way to answer this question.

IV. ACCUMULATING SYSTEMATIC ERRORS

The question now arises: Given the estimates for the maximum limits of all non-negligible systematic errors which must be taken into consideration, how is their effect on the measurement estimated? If the systematic error of a measurement is dependent upon several systematic errors whose estimated maximum limits are given, how are they combined to yield the systematic error of the measurement?

For a general discussion of the treatment of systematic errors, let a system measuring the Quantity Q be described as $Q = f(a, b, c, \dots)$, where a, b, c, \dots are components of the system representing the known quantities A, B, C, \dots . The magnitudes of these systematic errors have been estimated to be not larger than e_A, e_B, e_C, \dots . The propagation of error equation then gives the relative contribution of each systematic error term to the resulting

taking the measurements over a prolonged period of time, the systematic error of each group was allowed to vary and to become part, the major part in fact, of the random error of the measuring process.

Reference 1 describes the phenomena of errors changing their nature in the following terms: "If the cause system is enlarged, then what was previously predictable bias may,

systematic error as

$$|e_Q| = \left| \frac{\partial Q}{\partial a} e_A \right| + \left| \frac{\partial Q}{\partial b} e_B \right| + \dots + \left| \frac{\partial Q}{\partial i} e_i \right| + \dots + \left| \frac{\partial Q}{\partial n} e_n \right| \quad (1)$$

provided the errors are mutually independent.

The application of the propagation of error equation (Ref. 5) is illustrated in the Appendix.

Mindful of the facts that systematic errors are usually quoted as " $\pm e_i$ " or " $+e_{i1}, -e_{i2}$ ", i.e. with a positive and a negative limit, and that they can be only positive or negative, but never both, metrologists have tended to devise methods to reduce the purely additive effect of the individual terms of equation 1. The most commonly used method to reduce this purely additive effect of errors is the rss-method by which the individual terms are squared and the square-root of the sum of the squares used as the estimate of the overall uncertainty. The conscientious metrologist will in the vast majority of cases avoid such an arbitrary reduction and adhere strictly to the additive form of the individual terms of that equation as written.

Youden⁽¹⁵⁾ has shown that the combination of error terms in quadrature yields erroneous results in a chain of laboratories because it is deficient in logic. (See also Ref. 10.) In fact, any method to reduce the combined effects of several systematic error terms is arbitrary and can seldom be justified logically for the following reasons:

1. Individual systematic error terms come from different populations, distributions, having different origins and means, and are unrelated.
2. In most practical problems, the number of separate, individual error terms is small, and the probability that all error terms have the same sign is appreciable; four error terms still have a 12.5 percent chance of ganging up with the same sign, and the consistent metrologist will not quote 3-sigma limits of uncertainty on the random error and take a 12.5 percent chance on the systematic error.
3. Although systematic errors are mostly believed to be overestimates, they may also be underestimates - and frequently are.

But this problem appears to be more a theoretical than a practical one. In accordance with Juran's principle of "the vital few and the trivial many", in most practical cases only a few individual component errors determine the magnitude of the resulting overall systematic error, while the others are of little or no consequence.

Thus remains to consider the theoretically possible but rare case of a large number, say ten or more, of systematic error terms of approximately the same magnitude where some mutual cancellation is likely to occur. In this case, the critical metrologist will accept any logical rationale to reduce the total error to something less than the sum of all individual terms. However, prudence and consistency would dictate that the resulting total error be not less than the sum of the nine largest individual terms when three-sigma limits are quoted for the random error and not less than the sum of the six largest individual terms when two-sigma limits are quoted for the random error.

V. KEEPING MEASUREMENT ERRORS UNDER CONTROL IN A STANDARDS LABORATORY

A standards laboratory involved in certifying standards for lower echelon laboratories must make considerable efforts to keep its errors under control. Ordinarily, it does not suffice that the measurement errors are determined periodically and that it is assumed the errors thus determined are typical and recurring at the same magnitude. A positive proof that the random error of a measurement was indeed typical and that no unusual systematic errors have occurred during the measurement would go a long way in enhancing the laboratory's confidence in its measurements and contribute significantly to an eventual reduction of realistically quoted limits of uncertainty.

Quality control practices, time proven and honored in production processes, provide us with excellent tools for the observation of the quality of measurements: Control Charts. "Measurement of some property of a thing is ordinarily a repeatable operation. This is certainly the case for the types of measurement ordinarily met in the calibration of standards and instruments. It is instructive, therefore, to regard measurement as a production process, the 'product' being the numbers, that is, the measurement processes in the laboratory with mass production processes in industry."⁽⁴⁾ Reference 2 gives detailed instructions on establishment and maintenance of control charts.

Figure 5 is a hypothetical example of a control chart for a 1000-ohm standard resistor. The resistor serves as our standard and is periodically calibrated against a higher echelon standard. Its value is established by a Trend Chart. Each time we calibrate a 1000-ohm standard resistor for somebody else, we also measure one of our own 1000-ohm standards (in this case the one whose control chart appears in Figure 5) by the same process and using the same instruments, in a pilot measurement.

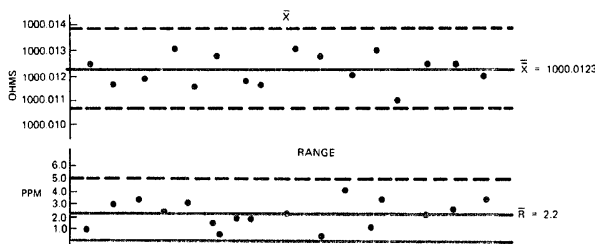


Figure 5. Control Chart of a 1000-ohm Standard Resistor (Measurements in Sets of Four)

Each pilot measurement consists of a set of four measurements taken at different times. The mean of each set of four is plotted on the \bar{X} -chart, and the range, the difference between the largest and the smallest measured values, is plotted on the R-chart. Upper and lower control limits are calculated as outlined in References 2 and 7.

Although occasionally a point may fall outside the control limits as a matter of pure chance, each time this happens the existence of some abnormality in the measurement is suspected, and the measurement is repeated. If the point of the repeat measurement also falls outside the control limits, the existence of an abnormality is taken as being confirmed. The causes for this abnormality are then determined, removed, and the measurement is repeated. If the points on the \bar{X} and the R-chart fall within the control limits, the measurement is considered valid. Since our customer's unknown standard was measured by the same process, its value thus determined is also considered valid.

Points of the \bar{X} chart will reveal the existence of short term trends or cycles, and unusual systematic errors. The R-chart is predominantly an indicator of the quality of the measuring process, reflecting, among other things, the care of the operator and the control of the environment in which the measurement was performed. Since a control chart is the result of a compilation of a considerable amount of data concerning one measuring process, the average experienced range \bar{R} can be used to determine the standard deviation of the measuring process. "Most experimental scientists have very good knowledge of the variability of their measurements, but hesitate to assume known σ without additional justification. Control charts can be used to provide the justification." (7)

The last point on the control chart for averages and that for ranges in Figure 5 represent the last calibration of 1000 ohm resistors performed by our lab. The average of the four measurements taken on the pilot resistor charted in Figure 5 was $\bar{X} = 1000.0121$ ohms and the range of the four measurements was then 3.8 milliohms. The recent grand average of pilot measurements made with this resistor is $\bar{X} = 1000.0123$ ohms and the average range is $\bar{R} = 2.2$ milliohms as plotted. Upper and lower control limits on the \bar{X} -chart of the averages are at a distance of

$$A_2 \bar{R} = 0.729 \times 2.2 = 1.6 \text{ milliohms}$$

from the grand average \bar{X} . Upper and lower control limits of the R-chart of ranges are at

$$D_4 \bar{R} = 2.282 \times 2.2 = 5.0 \text{ milliohms}$$

and

$$D_3 \bar{R} = 0 \times 2.2 = 0.0 \text{ milliohms}$$

respectively, as plotted. The estimated mean standard deviation of the calibration process which yielded these results is

$$\delta = \frac{\bar{R}}{d_2} = \frac{2.2}{2.059} = 1.07 \text{ milliohms}, \quad (2)$$

and the uncertainty of measured value of 1000.0121 ohms due to random error at 3-sigma levels is

$$3\delta_{\bar{X}} = \frac{3\bar{R}}{d_2 \sqrt{n}} = \frac{3 \times 2.2}{2.059 \sqrt{4}} = 1.6 \text{ milliohms}$$

The factors A_2 , d_2 , D_3 , and D_4 are tabulated in references 2 and 7.

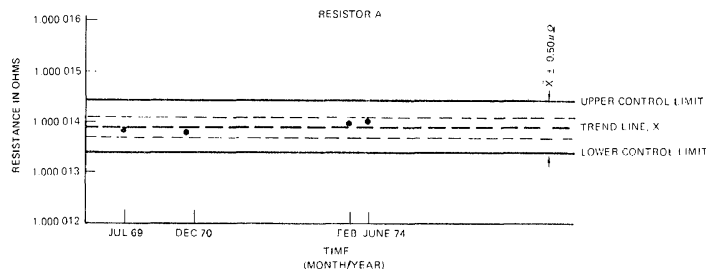


Figure 6. Trend Chart of Recent Values of Resistor A

The two last points, like the others before, fell within the control limits, indicating that no abnormal systematic or random error had occurred during the measurement and that the measurement was, therefore, typical for this particular process.

The distribution of the points in Figures 3 and 4 is not necessarily typical for normal laboratory comparisons between standard resistors where it is frequently possible to control the factors influencing the measurement (e.g. temperature) more closely and attain narrower uncertainty bands, i.e. narrower regions bounded by control limits.

The difference between the value of the standard as determined by the Trend Chart and the grand average \bar{X} on the Control Chart must be considered a systematic error of known magnitude and sign if the difference is statistically significant. A significant difference must be removed by adjustment or by applying this difference as a correction to all measurements made by the process under consideration.

The difference is statistically different at a level α , if it is larger than

$$\mu = z_p \frac{\sigma_{\bar{X}}}{\sqrt{n}} \quad (3)$$

where z_p is the standard normal variable or the ordinate of the normal curve for a cumulative area of p under the normal curve, and where $p = 1 - \frac{\alpha}{2}$.

Using Equation (3), we can now answer the question at the end of Section III C. Let us assume that the average range of the five measurements ($n=5$), was $R = 0.7$ milliohms. Choosing $\alpha = 5\%$ or 0.05 , $p = 0.975$. We first calculate $\delta_{\bar{X}}$ from Equation (2) as

$$\delta_{\bar{X}} = \frac{\bar{R}}{d_2} = \frac{0.7}{2.326} = 0.30 \text{ milliohms.}$$

Then, from Equation (3).

$$\mu = 1.96 \frac{0.30}{\sqrt{5}} = 0.26 \text{ milliohms}$$

Since the difference between our measured average and the certified value is 0.4 milliohms and, therefore, larger than μ , the difference is significant, and we conclude that a bias exists which calls for immediate correction.

To allow for changes in the systematic error contributed by the measuring process or the standard, the grand average must be updated periodically, at which time it may be necessary to omit some of the oldest points and recalculate the average on the basis of the latest points. Between 10 and 25 points should be available for calculating \bar{X} and R initially, and their values should be updated when additional groups of points become available.

VI. CONCLUSION

The majority of all sources of uncertainty which a metrologist normally encounters must be treated as systematic, even though many of them may have originated as random errors. The boundaries between systematic and random errors are fluctuating, and systematic errors may at times recover their random nature if we increase their "cause system", i.e. frequently the time period over which we consider them. The statistical treatments developed for the determination and analyses of random errors do not normally apply to systematic errors. We have seen how we can determine the magnitudes of systematic errors of standards and measurements, how we can control them, and how a control of the systematic errors, combined with a control of the random errors of measurements, can lead to a positive and definitive control of the

entire measurement process. Trend Charts for standards and Control Charts for measurement processes are invaluable tools for the sophisticated metrologist to enhance his knowledge of the behavior and uncertainty of his standards and measurement processes.

The emphasis is on collecting and analyzing information. Proper handling of data can then help to convert available information into a different form, but data manipulation cannot be a substitute for knowledge.

VII. ACKNOWLEDGEMENTS

The author is deeply indebted to Messrs. H. H. Ku and J. M. Cameron of the Statistical Engineering Laboratory of NBS as well as to their colleagues in the SEL not only for their efforts in reviewing an earlier draft of this paper and for their valuable comments pertaining to it, but also for the guidance which this group has given, and continues to give, to the author as well as to a great many metrologists throughout the nation in matters relating to the application of statistical methods to measurement data. A great many thanks also to Messrs. C. Peterson and Wells, then at the Resistance and Reactance Section of NBS, Messrs. Beers and Tucker of the Length Section, and Messrs. Belecki and Wells of the Electrical Reference Standards Section for providing important information without which some analyses presented here would not have been possible. The author is especially indebted to Mr. Kenneth Lund of Autonetics' Metrology Laboratory; his many suggestions and comments of a technical and editorial nature have greatly contributed to the improvement of this article. Any errors of commission or omission which may have inadvertently slipped into this paper, however, remain the sole responsibility of the author.

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Example on Accumulating Systematic Errors

This example illustrates the calculation of the systematic error incurred in measuring the value of a 1 gigaohm resistor (X) against a 100 kilohm standard resistor (A) whose value was determined earlier with a total uncertainty of 0.018%. The apparatus used in the measurement is a differential high resistance bridge shown in Figure A.

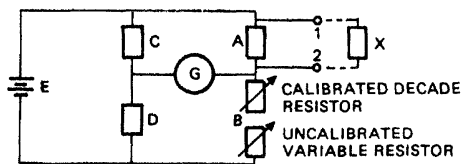


Figure A. Differential High Resistance Bridge

This bridge is first balanced with resistor X connected to terminals 1 and 2 and with the calibrated decade resistor set to zero ($B_1=0$). Resistor X is then disconnected and the bridge balanced again by increasing the resistance of arm B by an amount B_2 , using the decade resistor. The measured value of X is then

$$X = \frac{A^2}{NB_2} - A \quad (A)$$

Hence,

$$X = f(A, B_2, N).$$

The values and uncertainties of the individual elements of Equation (A) are found as tabulated in Table I.

Table I. Values of Elements, Equation (A)

Element	Measured Value	Total Uncertainty of Measured Value		
		Symbol	in %	Magnitude
A	100 005 Ω	e_A	0.018%	18 Ω
B_2	9.9005 Ω	e_B	0.27%	0.027 Ω
N	1.000	e_N	0.011%	0.000 11

Applying Equation (1) where Q now must be replaced by X of Equation (A), the systematic error of the resistance measurement due to the uncertainty of the bridge elements then becomes:

$$e_X = \left| \frac{\partial X}{\partial A} e_A \right| + \left| \frac{\partial X}{\partial B_2} e_B \right| + \left| \frac{\partial X}{\partial N} e_N \right| \quad (B)$$

The partial derivatives of X with respect to A, B_2 , and N are then respectively,

$$\frac{\partial X}{\partial A} = \frac{2A}{NB_2} - 1, \quad \frac{\partial X}{\partial B_2} = -\frac{A}{NB_2^2}, \quad \frac{\partial X}{\partial N} = -\frac{A^2}{N^2 B_2}.$$

so that (B) becomes

$$e_X = \left| \left(\frac{2A}{NB_2} - 1 \right) e_A \right| + \left| \frac{A^2}{NB_2^2} e_B \right| + \left| \frac{A^2}{N^2 B_2} e_N \right| = \left(\frac{2 \times 100\,005}{1 \times 9.905} - 1 \right) 18 + \frac{(100\,005)^2}{1 \times (9.905)^2} \times 0.027 + \frac{(100\,005)^2}{1^2 \times 9.905} \times 0.000\,11 = 3\,226\,834 \text{ ohms or approximately } 3.2 \times 10^6 \text{ ohms.}$$

The value of X, using Equation (A), calculates to be $1.009\,6 \times 10^9$ ohms, so that the limits of uncertainty due to systematic error of the bridge circuit and the standard are at $\pm 0.32\%$.

QUALITY - A TRUE TEST OF MANAGEMENT

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Over the past several decades, many tests have been devised for determining the effectivity of various levels of corporate managers; however, in the final analysis, the unit of measurement most frequently used has been the dollar on the bottom line of the profit and loss statement. As a matter of fact, with few exceptions, the dollar remains as the basic unit of measurement of managers at all levels, including managers of Quality and Reliability. I take no issue with this; however, the effect of poor quality frequently does not show up on the bottom line immediately and managers may not realize the ultimate effect of poor quality until it is too late.

Although every industrial manager plays a definable role in the quality of goods produced, and despite the fact that it is the main part of every quality manager's job, the key individual in producing high quality products is unquestionably the General Manager. Without his commitment to product quality, and his support when the going gets rough, even the most professional Quality Control Manager can do very little in preventing the manufacture and shipment of substandard products. If, on the surface this seems to sound strange, let us probe more deeply.

It has been widely said that "quality is everybody's job" and, conversely, it has been widely demonstrated that "everybody's job is nobody's job"; therefore the buck must stop somewhere.

Engineering must design a product which can be produced economically and which will satisfy the customer's expectations; Manufacturing must maintain the design in fabricating the product; Quality and Reliability must assure that the integrity of the design has been maintained; and Marketing must sell the product only for those applications which will be satisfied by the designed performance. Therefore, if a part of everybody's job influences product quality to varying degrees, someone must coordinate and put it all together - The General Manager. The buck stops there.

I have been intimately acquainted with the professional performance of many quality managers; yet, in my opinion, rarely does one exist who is not capable of doing a much better job than he is permitted to do, even within the fiscal restraints of his budget. Equally as rare is the general manager who does not loudly proclaim his dedication to product quality; however, if the past performance of general managers had matched their verbal protestations, there is some reason to believe that acronyms such as CPSC, OSHA, DOT, and EPA might be substantially less prolific.

History has taught many lessons regarding product quality, but little seems to have been learned. In good times and bad times alike, there has always been a great demand for products with a reputation for high quality. In the depression of the 1930's there was a substantial demand for Cadillac motor cars, just as there was in the recent sales downturn of 1975. What rebate was offered on the purchase of a Cadillac in 1975 when others were offering \$400 to all takers if they would buy brand "X"?

Quality is easily recognized and sells with little huckstering. Despite the fervent wishes of many of those on the commercial scene today, consumer awareness is not going to decrease; rather, it is increasing rapidly. The well known television commercial which advises, "Promise her anything, but give her Arpege" may very well sell perfume; but a manufacturer who takes such advice literally concerning his product, will soon learn of his error, and perhaps disastrously. All too recently, consumers all over America demonstrated that they couldn't be promised a higher priced automobile and then be delivered a car with a lower priced engine. Today's consumer will be satisfied with nothing less than a product which fully lives up to his expectations, and he becomes quite visible and vocal when a product falls short of its advertised performance.

The author has been a quality professional for over 40 years, and honesty, integrity, and high ethical standards of conduct have always seemed very important to him. Unfortunately, some of the supervisors to whom he reported did not entirely share the same degree of value he placed on those elements of stewardship. Blessed is the General Manager who has learned the value of high product quality, and doubly blessed is the Quality Manager who has such a General Manager.

In many instances the author has enjoyed some excellent general managers who not only permitted him to do his job, but also gave him every bit of encouragement and support he could ask for; yet, too many previous supervisors seemed to lack the talent to lead a manufacturing team through the pitfalls of production difficulties. Instead of taking the lead in solving production problems, they could only insist on the acceptance and shipment of shoddy products that did not measure up to the designed, advertised and certified standards.

It might be understandable if the author was a rigid conformist, who unyieldingly insisted that parts were not acceptable if there was even the slightest variation from blueprint dimensions. Rather, he has always maintained a pragmatic approach to design deviations and, if conservative engineering judgement indicated "fitness for use", there was no question as to acceptance. Use the parts but adjust the process so that future production would comply!

Practically every Quality Manager is able to cite varying numbers of traumatic experiences wherein he has agonized over the anticipated effect of having his professional judgement overruled by his supervisor.

It is with substantial concern that the author has noticed what seems to be a significant downward trend in individual ethical performance, not only at the General Manager level, but at all levels of management. The maintenance of a high standard of ethical performance is never the easiest course of action, and rarely the most pleasant one. Worshipping at the shrine of expediency has reached endemic proportions, and the self-discipline necessary for doing the unpleasant seems to be a steadily vanishing characteristic in all walks of life.

Each of the professional, engineering, and technical societies has an excellent Code of Ethics which has been refined over the years so as to embody only the highest ideals of integrity, morality, and stewardship. The American Society for Quality Control is no exception.

Everyone fully subscribes to these Codes of Ethics and the principles they reflect; however, in too many instances, there seems to be an inadequate effort to apply them to the difficult business decisions every manager is called upon to make each day.

Today's colleges and universities have done very little to include ethics education into their professional and business curricula and, unless there is a concerted effort to make students more aware of the conflicts they will inevitably encounter in their professional careers, sufficient enthusiasm will not be generated for establishing ethics courses.

When incoming inspection of purchased items reveals that substandard quality has been received, it has become almost automatic to assume that the supplier has an inadequate quality control system which does not properly catch defective products. Additionally, the notification of rejection will also ask what the supplier will do to improve his quality system so as to preclude a recurrence. Perhaps we should not be too hasty in making such assumptions.

One cannot help but wonder how many of these instances, if the truth were known, were not caused by the failure of the supplier's quality system to identify the unsatisfactory product but rather because the General Manager overruled the rejection by his Quality Manager and ordered the material to be shipped regardless of the known unsatisfactory condition. It has happened frequently, and will continue to happen as long as it goes unrecognized, ignored and tolerated.

When a professional Quality Manager must operate in such an environment, one of three things must happen: 1. The Quality Manager must develop an infinitely elastic and convenient conscience; 2. He must attempt to chart a most difficult if not impossible course of ethical conduct which will permit him to retain his employment, and thereby accept the potential risk of violating his professional code of ethics; or 3. Seek another less frustrating environment.

In either event, considering the tremendous hazard of legal liability which hangs as the Sword of Damocles over the head of every Quality Manager, it seems most judicious that he maintain a bound ledger or log book concerning those cases in which his professional judgement was overruled. Each item should be dated and give a full account of all particulars of the matter including the item involved, the quantity, a description of the product quality deviations, the degree to which it was present, the name of the individual who directed acceptance and/or shipment of the items which were known to be defective, and any other pertinent data having a bearing on the matter.

Now in order to preserve some semblance of fairness, the question of overriding the Quality Manager's decisions should be examined from the viewpoint of the General Manager.

It seems quite reasonable to assume that no one, even Quality Managers are so infallible that their decisions are invariably correct. Additionally, in some circumstances the General Manager may have pertinent information which is not available to the Quality Manager and, in rare instances, information so confidential that it may not be revealed. In those instances, the General Manager's veto action may very well be entirely justifiable; however, if such instances occur somewhat regularly, it seems reasonable to conclude that either the Quality Manager is somewhat less than optimally effective, or the outgoing product quality level is leaving much to be desired.

No manager's job is an easy one, but quality is a true test of management.

LCS 310:10:000

WHY CALIBRATE OURSELVES TO DEATH?

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For many years we've been involved in all kinds of calibration programs. They're not only required by various regulating documents; why, even common sense demands them.

This presentation isn't made to demean these efforts. Rather, my complaint is directed toward the overwhelming complexity and costs of programs based primarily on periodic recalibration. Those costs might be justified if they honestly satisfied our single primary objective; namely, acceptance of only those products meeting their design criteria. Too often, the objective is missed regardless of the efforts expended: We initiate elaborate procedures to detail the turn of each button or handle for every measuring instrument we use, be it electrical, mechanical, hydraulics, or what have you. Then we set up time cycles for re-verification of those characteristics. Next we initiate "trend charts" to identify needs for shortening the cycle and to identify possibilities of cycle lengthening where appropriate. The fallacy is that all these exercises are attuned, not to the direct acceptance of a quality product, but to statistically arrive at a magic span of time within which an instrument will probably remain "in tune". I say probably, simply because the cycle ignores the damages caused by an instrument being dropped on a concrete floor or getting caught in a machine. We certainly want to minimize these damages.

To begin, let's "Value Engineer" the task for a minute: If the calibration program we propose actually validates the authenticity of our product acceptance examinations, then we've accomplished our basic objective. No matter how bare, no matter how frugal it is, the program has to be recognized. Maybe it doesn't meet all the little tricks, controls, and niceties of some particular specification; but then if we plan a little deeper, maybe it can. There's no magic involved; let's just examine the possibilities of simplification by modifying applications of the term "periodic". All the Standards I know read something like, "Shall be calibrated at specified maximum periods of time, or use".

Summarily, my proposal is to assign, wherever feasible, to the instrument user, the inspector, the machinist, the technician, complete responsibility for checking the accuracy of the instruments he uses. This checking is done to "work", "reference", "secondary" standards, or whatever you want to call them, and these standards then, instead of the instruments, are periodically checked in the normal fashion.

My first exposure to an honest, direct, and effective calibration program was back during World War II at a gear manufacturing organization. The company fabricated a high percentage of precision aircraft gears used by Wright Aeronautical and Pratt and Whitney. Both machine operators and inspectors used their own personal standard mechanical measuring instruments for most verifications. Each time a machinist set up to run a particular operation, he took his instruments to a gage crib (sometimes the day before) with the process drawing of the dimensions he was to generate. The tools were then set to those exact dimensions and paper slips were initiated identifying the part number, operator number, dimensions, date and the gage inspector who did the setting. Likewise with the bench inspector who checked each individual part prior to the next machining operation. Both operators and inspectors were required to maintain the calibration slips in plain view at their work site.

The Gage Inspectors literally worked their "Masters" off; but during five years as Quality Engineer with the company, I know of no recorded incidents of any serious deficiencies traceable to inadequate calibration control. Oh, we had the usual problems, like a surplus of discrepant "set-up" pieces, breakdowns of heat treat cycles, too much or too little grind stock, sloppy fixtures and the like, and we had some run of human problems too.

An Air Force Inspector stopped at an inspection station where a young lady inspector sat, surrounded by boxes and skid-loads of gears. She was using a Rockwell Hardness Testing Machine to test core hardness. She carefully wiped each gear, placed it on the anvil, flipped the lever, waited until the handle stopped, released the pressure and removed the gear. The Air Force representative asked, "And what is your job here young lady? It looks very important". The young lady took a gear out of the tester and turning on her stool, handed it to the representative: "You're darned right it's important. See that little bitty hole? I have to put a hole like that in every single one of all these gears before we ship them".

Anyway, after exposure to 100% calibration, I moved to the Ford Motor Company, Aircraft Engine Division, to build Pratt and Whitney Aircraft Engines. The calibration program here was entirely different, with all M and TE (measuring and test equipment) on periodic cycles varying from each work shift for some to annual on others. Funny, how much faster the "GO" members always seemed to wear out!

The total number of different micrometers as a single equipment item, reached into the thousands. They were controlled by what was then known as the "Three-Card" System. Card Number 1, filed in a Master Gage Lab, identified an inventory number assigned after receiving inspection acceptance, and carried the plant work area crib number to which the instrument was assigned. Card Numbers 2 and 3 were kept in the work area cribs with the instrument. Card Number 2 recorded, along with the inventory number, the model, etc., and wear tolerance, results of inspections, inspector identification, and the next due date. It was filed by inventory number. Card Number 3 containing identical information, was maintained in a "calendar tickler" file set up by month, week, and day. The Number 3 or last card, then, identified the work load for the area gage inspectors for upcoming days, weeks and months.

I'm going through these details for a purpose - so that you can visualize the enormity of labor connected with such an operation, not only with actual calibration, but also with the clerical work of transferring card information. The plant had some twenty-seven area gage cribs, each manned by several gage inspectors and clerical support.

I really can't take credit for the next innovation that took place. Someone decided that checking of the standard instruments like micrometers could be more expeditiously checked right in the manufacturing work areas. The gage inspectors lost considerable time searching for people with micrometers signed out. The main reason for this was that machinists and inspectors preferred to keep the instruments locked up rather than check them in and out every day. In preparation for moving the gage inspectors out "to the action", we built some standard machined rings, pyramids, etc., to be used as work standards when mounted on push-wagons. Had I been in the wagon manufacturing business, I might have been successful; but since I wasn't, (who ever heard of a successful inspector?), I proposed that we forget about using them. Instead, and possibly to avoid responsibility for scrapping hundreds of fabricated "work masters", I had the fixtures mounted outside each gage crib window on a supporting shelf and hung a sign over them. The sign announced a new rule: "Users are responsible for their own instruments. Check your mike before you use it". The procedure dulled some of the "luster" from the lofty gage inspector jobs and turned them into part-time instrument repairmen. But, we were able to destroy the Number 3 cards for all micrometers, reducing the "worklog" volume by over 50%. Individual machine operators and inspectors didn't mind making their own checks but some gave the gage men fits because their personal 'feel' on a particular instrument was different than as adjusted by the last setting.

My "User" calibration program permitted a considerable reduction in workforce. The reduction turned out to be just a "token"--the entire plant closed down.

For eleven subsequent years, I worked for a company who had a much more elaborate and modern calibration program. Everything was on periodic cycles but IBM took care of all the bookkeeping. They hired one "Planner" for every four gage inspectors. The Planner initiated special check-sheet instructions for each and every type and size of measuring instrument. These check-sheets had to be meticulously and faithfully used by the gage inspectors, with all individual accepted characteristics stamped off exactly as if the employees were documenting a product acceptance rather than calibrating a standard measuring instrument.

Extremely advanced methods and equipment were installed including GE Electronic Gages to calibrate gage blocks. We had a few problems: We found that a female gage specialist needed approximately one hour to check a single Hoke block. This worked out to a cost of from 50 to 60 man-hours, plus a 133% burden rate for calibration of a 50-piece block set. We went back to sending the Gage blocks to the Naval Ordnance at Pomona. Then three more specialists were hired to "Trend" various wear patterns of different types of gages. The trends told us many things: Go, No-Go Plug Gage "A" at .9995/1.0000 didn't wear out for a long time, so the recheck cycle was extended from weekly to every two months. Problem--when calibration of all "A" plug gages went to two monthly checks as a result of the "trend" study, we got into some assembly problems because of undersized holes. Reason--while some of our "A" plug gages lasted for up to eight months, we had other applications of "A" plugs that wore out in about three weeks.

But progress will not be denied. The gage calibration program continued to expand and refine its procedures. In all honesty, we never had to spend as much money reinspecting hardware as we spent on the calibration program--that is if we didn't include the product rework/repair costs. Following are some possibly surprising facts: Inspectors very seldom bothered to check their instruments--why should they? Somebody else was responsible, not they. And as far as the gage inspectors were concerned, why fight City Hall? Work loads were pre-established so a micrometer got checked when the IBM said so and that's all. When damaged or worn instruments were discovered, so what? The "Trends" would take care of it and close up the period cycle. What's that old adage about "The best intents of men geng aft aglae?"

Some years later, up in Richland, Washington, I ran into a situation that really provided an opportunity to try my "category" idea. The Hanford complex was comprised of a family of AEC contractors, serviced by a small but top-notch calibration laboratory working under the auspices of one of the contractors, Batelle Northwest, who was also my employer. The trouble was the contractors didn't make much use of the lab, but rather tended to avoid it.

There were several thousand items of M and TE on several recorded contractor and divisional inventories. When an item was sent to the lab for calibration, it was placed on a period cycle. When the cycle was up, a notice was sent to the owning contractor division or department requesting submission for a re-check. The notices were almost always ignored. Can you imagine the stack of paperwork, notices, transmittals, second and third requests? The calibration lab barely managed to stay open. Its operating cost had to be charged direct, that is, to the department and contractor for whom the work was done; so - no work, no pay - very few people.

In defense of the contractor departments and scientists, they had their own reasons for ignoring the recalls. Some of them were reasonable. A small group of scientists working on say a six-month \$240 K experiment pulled out maybe 30/40 M and TE items from their division stock of possibly 800 to 900 items. They would send possibly 4 or 5 particular gages to the lab prior to making their test set-ups, but only if they thought their accuracies might be suspected to the extent of degrading their generated data. They didn't manufacture a product, they ran experiments and published results. Often they rightfully felt that so-called "built-in" accuracies were good enough for their needs. They would use a "set-up" of instruments continuously on a particular experiment for the six months and then maybe not again for a year or two. They bought their own equipment as chargeable to this or that experiment and the purchase included a supplier certification which was filed for reference over the years. So long as they kept the instruments to themselves, they could use it as they wished, but when they sent it to the gage lab for calibration, or repair, it automatically appeared on the recall IBM and was forever carried as delinquent while in truth it might have been out of use for months or even years.

My helper this time was the AEC; they demanded that Batelle up-grade their program. I officially initiated a "category" calibration program like this: First of all I decided that we only needed to identify and control gages actually being used, so we documented the fact that gages without labels would not be used in any experiment or machine work since they would be considered as strictly "in storage".



AL ACCURATE SEZ:

USE ONLY

MEASURING / TEST INSTRUMENTS
IDENTIFIED WITH "AL ACCURATE"
LABELS ON SPONSORED WORK.

BD-1060-030 (11-70)
AEC-RL RICHARD, WASH.

Department M & TE inventories came out of the woodwork and items were grouped into two categories:

Category "A" (white labels) identified instruments which the user, whether a technician, machinist, or physicist could check himself to some particular other available standard which then became a Category "B" (yellow label) and went on a regular periodic calibration cycle, albeit reasonably extended, since the B's were seldom used for actual experiment or machine shop work.

NOTE: Batelle quickly decided that "Al Accurate" was OK for machine shops but quite unsuitable for scientific level work, so he was swiftly buried and the labels more conventionally printed.

CALIBRATION

BEFORE
USE
REQUIRED



BD-1060-030 (11-70)

CALIBRATION

EXPIRES

DATE _____
S/N _____
DATE _____
TECH. _____



BD-1060-034 (10-72)

Now, only B's or yellows had to be calibrated, representing a very small percentage of gages actually being used. The costs were reasonable and more important, the program gave us a modicum of experimental accuracy not previously experienced.

Unusual aspects of the program included:

1. Presence of instruments without labels in work cabinets was OK, - Remember? - they were considered as "not in use". They just couldn't be used in any contracted work without first being categorized and appropriately checked.
2. Everyone had access to "A" (white) labels, but "B" (yellow) labels were only issued at the gage lab.
3. Ordinarily a category B gage was returned to the gage lab by the owner for recalibration upon regular notification. But if the owner didn't need the calibration any longer, all he had to do was remove and destroy the B sticker, automatically placing it into his "not in use" category. The Gage Lab procedure was revised to automatically drop a gage after a second recalibration notice. Whenever an owner wished to re-instate a gage as a B, he simply sent it to the lab where it began a new cycle program. An especially welcome example - a team of scientists used two identical oscilloscopes in a complicated multiple experimental electronic set-up. We had a third identical instrument calibrated at the lab and designated as a B. Daily the men checked the other two working units, labeled as A's against the B.

Strange as it may seem, the Richland, Washington, office of the AEC audited our new program and praised it - but not the first time. Remember - the backbone of the program is that the "user" must check his A's prior to use. If I ask a man working on an experiment, "How did you check that instrument?" and "What B reference instrument did you use?", the person must be able to (1) produce the B referenced standard and (2) demonstrate proficiency necessary to adequately make and evaluate the comparison.

On the AEC's first Batelle audit, several departments, including the machine shop, came through with flying colors; but on one little project experiment, a working scientist had put A stickers on every instrument including a set of blocks. His reasoning: "I bought the gages myself, for my own work and I have supplier warranties. I believe those warranties equate our gage lab checks." He passed OK on the next audit.

The Argonne Laboratory, as an organization, was a little like Batelle Northwest, but operated under the auspices of the University of Chicago on contracts for the AEC and more recently, the Energy Research Development or ERDA organization.

A preponderance of M and TE were on periodic cycle cards for calibration and on IBM runs for inventory accountability, but the IBM didn't carry calibration status.

In September of 1972, two file cabinets were full of calibration cards representing instruments, some of which hadn't been seen by the single assigned gage inspector for as long as four and five years. The Quality Control Supervisor, Inspection Foreman and I spent one weekend removing all labels from all instruments in the four working inspection areas - that is, from all inspection equipment. Two days later, three ERDA auditors appeared and most fortunately for me, one of them was a participant from the Richland, Washington, office who had reviewed and was familiar with the Batelle program.

We presented a single-page document, identifying a categorized calibration program basing primary responsibility upon the user supported, by appropriate reference masters under periodic cycles. The document was accepted with a 60 day commitment for inspection.

Announcements were posted describing the program, explaining the use responsibility concept:

N O T I C E

To: All Inspection Personnel

From: J. F. Wilcox

Periodic recalibration of micrometers and certain other common hand measuring instruments is hereby discontinued.

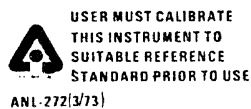
The accuracy of these instruments shall be the responsibility of each using inspector. He shall check his instrument to a suitable reference standard each time it is withdrawn from bench, drawer, cabinet or crib. Should anything be found wrong with the instrument, it shall be presented to the inspection supervisor for repair, re-set and/or replacement.

Quality Control will continue to provide requested calibration or repair of such instruments for production personnel.

Additional reference standards will be supplied to various shop areas in the near future for user convenience. The reference standards will be incorporated into regular periodic recalibration cycles.

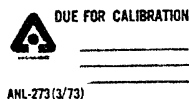
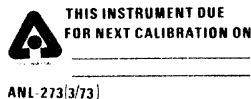
Categories were defined as follows:

CATEGORY A



Category A - Instrument which must be examined and calibrated by the user to suitable reference standards each time they are withdrawn, for use, from a tool crib, locker, desk, or other place of storage. These instruments are physically identified by the ANL Quality Assurance White Calibration Label (Form No. ANL-272), assigning such calibration responsibility to the user. Instruments found discrepant shall have identification removed and shall be submitted for repair prior to re-identification as Category A.

CATEGORY B



Category B - Instruments which require regular examination and calibration to references by other than the user. This category generally includes reference "standards" used for calibration of Category A instruments and also instruments requiring special setups/environments, arrangements, or equipment to accomplish the examination. These instruments are physically identified by the ANL Quality Assurance yellow calibration label (Form No. ANL-273). Label indicates calibration expiration date, serial number of instrument and name of technician.

NOTE: Accuracy of reference standard used must be traceable to U.S. National Bureau of Standards.

Certain entities not formally covered in the original Batelle program were addressed in gradual refining of the Argonne program. For example, the following direction dealt with items like V blocks, parallel bars, square and cube blocks:

"Assist or support tools must be visually inspected for any burrs, damaged edges, or other surface irregularities that could affect inspection results. All such irregularities must be removed by stoning or other appropriate means prior to use".

Category A instruments such as micrometers were required to be checked in four rotational thimble positions using set-masters, prior to use.

Category B instruments were calibrated to documented descriptive procedures, initiated for general classes or types to comply with the ERDA imposed Standard RDT Calibration F 3-2T.

During several years of continued operation, a few refinements, clarifications, and such have been incorporated, mainly as ideas submitted by the people themselves.

Those contributions tend to illustrate generated employee enthusiasm and their pride in fulfilling of regular calibration responsibilities. And, I truly believe that such pride is important to a successful Quality program, don't you?

LCS 760:70:439

PROCUREMENT QUALITY PLANNING AND CONTROL

William G. Gage Jr.
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A successful Procurement Quality Planning and Control program must start out as a plan itself. A planned Quality Assurance - Procurement team effort must meet with all potential sub-contractors and suppliers on all levels of management and during the various phases of development and production to define and refine the planning and controls necessary to any project undertaking.

To digress momentarily, we must define several very critical concepts: First, there should be a written procurement quality policy which states "This company will deal only with sub-contractors and suppliers who are:

- (a) Capable and well qualified,
- (b) Understand the requirements,
- (c) Are willing to adhere to the requirements"

Second, Quality Assurance functions are NOT responsible for Supplier quality, Procurement specifically the Buyer or Purchasing Agent, is responsible for quality; Quality is a balance of:

- (a) Compliance to Technical requirements
- (b) Competitive pricing
- (c) On time delivery

Third, Procurement must take the lead in strengthening Supplier performance:

- (a) Responsibility for Supplier Quality lies with the Supplier, his personnel are responsible and his management must make it mandatory,
- (b) "True-Cost-Of-Purchase is the sum of all costs including; receiving, inspection, testing, rejecting, returning, plus Re-receiving, Re-inspecting, Re-testing and other like costs

Fourth, Procurement must assure the Supplier's understanding of their responsibilities, which include:

- (a) Planning for the total satisfaction of contract requirements
- (b) The burden of proof for Quality lies with the Supplier,
- (c) Certification and delivery of acceptable quality levels,
- (d) Quality conformance is submitting only items that meet all the requirements,
- (e) "Running his own Show", no Supplier should sit back and expect the Buyer or Buyer personnel to give him a push or run it for him.

With all these items you may be wondering, "What is the Procurement Quality Assurance role?" Procurement Quality Assurance is needed to:

- (a) Assure that the technical and contractual requirements are properly defined in the request for proposal,
- (b) Participate in the evaluation and selection of qualified suppliers,
- (c) Help suppliers understand requirements,
- (d) Evaluate compliance to requirements,
- (e) Identify causes of variability and act to eliminate them,
- (f) Participate in non-conforming materials control and disposition,
- (g) Rate supplier performance and conformance.

Every Procurement Quality Assurance action is aimed at the primary goals of delivering a product or service that meets the requirements fully, on schedule and for the quoted price, which provides a fair profit for the supplier.

Now, back to the planning and control function. Procurement Quality Assurance planning must be a carefully integrated portion of the entire procurement cycle. It must mesh with and support the overall objectives, it must be results oriented, it must be systematic and it must be cost effective. A planner, be it a Quality Engineer, Quality Manager, or Quality Analyst, must carefully and methodically think through the require-

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ments and develop a step-by-step program which will assure that the final plan will contain all the necessary functions to meet the requirements and objectives. The planner must assure that all the alternatives have been considered and the best for the circumstances selected. An important part of planning is the consideration of contingency factors, the "What If" items, those items which fall into this category which prove to be significantly important should have a contingency plan developed and ready for use, should the need arise.

There are several steps which are vitally important to a Procurement Quality Plan:

- | | |
|------------------------------------|-----------------------------------|
| (1) Requirements Definition | (7) Source Appraisal |
| (2) Supplier Evaluation | (8) Corrective Action Program |
| (3) Supplier Selection | (9) Failure Investigation |
| (4) Pre and Post-Award Conferences | (10) Source Inspection and Test |
| (5) Product Quality Plan | (11) Receiving Inspection Plan |
| (6) Surveillance and Audits | (12) Supplier Performance Ratings |

Requirements Definition- Defining the requirements makes a close relationship with Program Management and Design Function personnel mandatory. The relationship must be built upon mutual respect for each others abilities, an understanding of each others functional responsibilities and the realization that the decisions of each has a profound effect upon the project results. All requirements must be spelled out in sufficient detail to eliminate any doubt but at the same time must be kept concise and brief. Requirements must follow a standard format and include all aspects of equipment, testing, and qualification specifications.

Supplier Evaluation- All responding suppliers will require an evaluation of some type. Possibly it will consist only of the review of the proposal response, but if it is one of the finalists (especially on large contracts) a qualification survey and on-site review of the facilities and capabilities will be made. Additionally, a review of past history and supplier performance ratings should be made. The performance of a survey is to assure that the management systems employed provide the proper management and procedural controls to assure adherence to contractual requirements. A review of past history provides insight into the implementation and results of the system application.

Supplier Selection- The supplier finally selected will be the results of the Procurement-Engineering-Quality evaluation of Technical, Pricing, Contractual responses plus Capability Ratings. The selection will be a blending of the Technical requirements, Price, Schedule and Quality that satisfies the Buyer's needs.

Pre and Post-Award Conferences- These conferences are hard to define, some companies have both and they are formalized, while other companies have neither or they are very informal and then there are all combinations in between. To avoid a waste of money and time, if a conference is necessary, it should be formalized at least to the point of having an agenda, to assure that all points are covered. This agenda should have inputs from all functions of both the Supplier and the Buyer. There should, also, be a set of minutes published setting forth the discussions and their results and all agreements and interpretations recorded for future reference. Pre-Award conferences are particularly sensitive situations and must be handled carefully. Each participant must be given exactly the same information about requirements or other factors to prevent any possibility of giving an unfair competitive advantage to one participant or another. Also, extreme care must be exercised to prevent revelation of confidential information being communicated via a discussion which would expose proprietary information of another participant. Post-Award Conferences should use carefully prepared presentations which set forth and re-iterate the agreed upon goals and objectives. In all conferences, each item that comes up for discussion should be discussed forthrightly and openly, there should be no "beating-around-the-bush", "weasel-wording" or "double-talk", if something needs saying it should be stated plainly, with a spirit of clearing up the facts, so as not to lead to misunderstanding or mistrust at a future time.

The Product Quality Plan- This plan is the connecting link between the Total Quality System and a specific product. It is the application of the Quality System to the manufacturing processes which produce the characteristics of the product. The plan must identify the major tasks, how the tasks will be controlled and a schedule for accomplishment. A flow diagram must be created which identifies the routing of the product through the conversion process, origination of critical characteristics, the inspection and test points, along with references to procedures, instructions and test plans.

Surveillance and Audits- Surveys and audits are used to evaluate the implementation of the Quality System and the Product Quality Plan. Since it is impractical and uneconomical to duplicate inspections and tests performed by the Supplier, one of the better methods in use is the surveillance of the overall operations and audit of "key points" in the hardware or process cycle for results. Review and evaluation of Quality procedures, instructions and data for proper application and interpretation. Hardware inspections and functional testing activities need to be kept at a minimum by the Buyer, in all but the most critical or complex cases. Special case instructions and support need to be created regarding the witnessing of environmental and qualification testing by Buyer personnel.

Source Appraisal- How well a source is performing is accomplished through analysis and review of reports, results of Source Control Plan audits, supplier Quality Conformance and percentage of product that is received "assembly-ready and fit-for-use". The single most important action from Source Appraisal is the report to Management and Procurement of the results of the appraisal, on a timely basis. These same results must be fed back to the Supplier Management, both good and poor performance, and in the case of poor performance a request for corrective action and improvement.

Corrective Action Programs- Whenever sub-standard quality items are identified the corrective action system is activated. Procurement Quality Assurance is responsible for detection and reporting discrepancies, Procurement is responsible for correction and initiation of action. Procurement Quality Assurance makes recommendations, Procurement makes decisions. Procurement Quality Assurance and Procurement, jointly, seek identification and elimination of the causes of problems at the Supplier's facility (Procurement Quality Assurance acts as the consulting expert, drawing on the expertise of Engineering and Other Functions, as needed, to further the investigation and resolution). Corrective Action is requested by Procurement, on every discrepant item, and it is coordinated at the Supplier by Procurement Quality Assurance. The reaction and importance attached to a corrective action request, by a supplier, is an indication of his integrity and sincerity. Followup on implementation and effectiveness of solutions is carried out by Procurement Quality Assurance, who reports results and confirms that the problem has been resolved, and no apparent side-effects have appeared, to Procurement, who then closes out the Corrective Action Request.

Failure Investigations- Failures of all types are usually investigated by Engineering personnel, with Procurement and Procurement Quality Assurance assuming supportive roles. An investigation should be initiated on each failure identified as "Supplier Responsible". Whenever possible, failed item exhibits should be returned to the Supplier so his personnel can analyze, first hand, and take action to eliminate the cause of the problem. If it is impossible to return the item (due to its destruction, etc.) a very detailed description of the circumstances existing at the time of failure, should be given. Procurement Quality Assurance representatives can coordinate the investigations and supply additional information and details which may be required by the supplier. The Procurement Quality Assurance representative can provide the Buyer investigators, an insight to the suppliers internal operations that, many times, will provide a clue as to which direction an investigation should take.

Source Inspections and Tests- In process and final inspection of hardware and functional testing, when required, provide the basis for preliminary acceptance of the hardware, monitors configuration, records functional conformance data, and assures proper recording of deviations and Material Review Acceptances. This is partially accomplished through review and monitoring of quality records, inspection documents and test reports. The results of general surveillance activities and audits of in-process hardware contribute to the confirmation process and finally the witnessing of mandatory checks and tests involving the more critical and complex characteristics, completes the cycle of assurance. Results of all acceptance activities are reported to both the Buyer and the Supplier. Of course, the Corrective Action System is brought into play should there be any anomalies or defects.

Receiving Inspection Plans- Proper procedures should be carefully established for all major equipments. Material and equipment which has been Source Inspected and tested need not be given more than a cursory inspection to identify that it is the proper equipment called for by the purchase order and that there has been no shipping damage incurred. All other materials and equipment should have planned inspections and tests carried out to the detail necessary, as dictated by the criticality and essential nature of the item.

Supplier Performance Ratings- The rating system must draw data from all areas of activity and then process this into a meaningful statement of the supplier's status.

An often overlooked source of data is the post assembly and post delivery periods. Because, these, more than any other, indicate the degree of success attained from the previous planning and control efforts and provide indicators for future changes and improvements for the system.

Probably one of the hardest lessons to learn regarding Procurement Quality Planning and Control, is the "Plan" is never completed and "Control" is never assured. Because of the dynamic nature of change and technological advancement the Plan must be under constant review for several reasons:

First, that product changes, both engineering and process, must be reviewed for effect upon present procedures and techniques.

Second, an evaluation must be made periodically to support continuation of inspection and test performance. If, after a suitable period of time or quantity of units, no discrepancies are found, then serious consideration should be given to the use of some form of sampling or reduced sampling, or to the outright elimination of the function.

Third, on matured products or processes care must be exercised that careless or inadvertent mistakes and errors do not creep into the process and subvert the entire control network. The price of Quality is constant vigilance.

Fourth, from time to time, products and processes should be reviewed for new technology applications and improvements.

In summary, Procurement Quality Assurance Planning establishes the details of product complexity, levels of Procurement Quality Assurance involvement, needs for controls, and determines the manufacturing skills required. Procurement Quality Assurance participates in Supplier Capability appraisal, evaluation and selection. A coordinated plan provides a vital communication link; a means of servicing a Supplier's needs for interpretation of requirements and timely coordination of problem resolutions; and a means of measuring performance. A close working relationship with the Procurement Quality Assurance representative provides a rapid means of establishing Acceptable Quality levels and making improvements through constructive criticism. The On-Site representatives provide a surveillance and monitoring function of Material Review activities and assistance with deviation and waiver requests. In addition, these representatives act as an early warning system, giving advance warning of schedule slippages, raising questions regarding possible manufacturing difficulties due to design or materials and alerting Buyer management, when there is laxity of Supplier management concern regarding problems. A well conceived Procurement Quality Assurance Planning and Control System can provide a continuing reporting and management support function which will highlight potential problem areas, contribute to the resolution of these problems and help assure the hardware delivered meets the requirements, is on time and is delivered at the most economical cost.

310:70:439

ERROR REDUCTION IN THE JOB SHOP

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INTRODUCTION

Small lot sizes often found in the job shop present a challenge in controlling quality since well known analysis techniques lose their statistical significance in measuring variation. Most techniques have been developed for large quantity manufacture.

This paper will present a simple, inexpensive, possibly unconventional system which is helping to reduce scrap and salvage dollars and lost hours. It is of course important to remember that no system is a substitute for trained operators, capable processes and producible designs.

PROBLEM

The job shop under discussion exhibited a final inspection rejection frequency of 30-40% with 10-15% of machine shop hours lost due to scrap and salvage. Management concern and requests for solutions were abundant.

CAUSES

Trend analysis of rejection causes indicated operator error was the classical maldistribution phenomenon of the few causing a disproportionately large effect on the whole. Further study indicated that lack of attention and lack of knowledge were the primary causes of operator error. Contrary to the belief of some, it was not "bad attitude" or "rookies" that were important causes. In interview after interview with operators where sizeable errors were discussed, it was evident that the twenty-five year veteran had more errors than he thought he should and that he had a very positive attitude in wanting to do better. This could have been expected since these same causes are well documented in the literature. Halpin mentions these same two causes of operator error in his well written classic on Zero Defects.¹

SYSTEM

In formulating the system specification requirements some unique requirements began to emerge. A process control technique was needed particularly oriented to operator usage with a minimum of training and supervision. The technique had to be insensitive to part configuration, machine tool and years of experience.

It was clear that the operator needed help in planning each job systematically in a manner that would discover errors of input to the operator as well as errors of output or operator caused.

The thinking then turned to such questions as:

- How does the skilled operator keep himself out of trouble?
- What questions does he ask himself?
- What items does he check?
- When does he ask for help?
- How does he double check the job and himself to eliminate errors?

At this point a list was developed which built upon the above questions with checkable items. The further the list developed, the more it resembled a pilots check list prior to takeoff. The thinking behind each was the same.²

The list further developed along lines of job areas where possible variation could be expected which would cause error if not detected and resolved. The areas generally broke down into the following:

- 1) Blueprint, specifications, process and bill of material.
- 2) Tools, fixtures, gages, layout, setup and methods.
- 3) Piece parts, materials, supplies.
- 4) Process equipment, machine tool and special equipment.
- 5) 1st piece inspection.
- 6) Operator in-process inspection.

So called Job Check cards (FIGURE 1) were then color coded and printed for each of the following processes:

Machining	Red
Welding	Black
Assembly	Green
Electrical	Blue
Paint	Purple
Packaging	Brown
Crating	Orange

Color was used for easier identification as well operator esprit de corps. The cards are printed on oil resistant heavy paper with smear proof ink and a hole is punched for hanging.

The Job Check "man" replacing the "K" in the word check was designed and became the logo for the entire program and appears wherever the system name of Job Check is used. (SEE LOGO PICTURED IN FIGURE 1)

CORRECTIVE ACTION & FEEDBACK

The problems discovered by the operator using Job Check analysis required a simple, effective and timely corrective action and feedback system. The four part Job Check Problem Report was developed with the following features: (SEE FIGURE 2)

- 1) Job information such as part number and operator.
- 2) Description of problem.
- 3) Area responsible for corrective action.
- 4) Description of corrective action by responsible area.
- 5) Effective date of corrective action.
- 6) Employee responsible for followup of corrective action effectiveness.

The problem report was designed with one hard back copy and three thin "snap-out" copies.

JOB CHECK PROBLEM REPORT							
RC#	OP.	MACH. #	OPTR. NUM.	FOREMAN	PART NAME	PART #	
EXPLAIN PROBLEM:					DEF. CODE	CAUSE CODE	FO/MA
						OP/CHK	
RESPONSIBLE AREA: DESIGN <input type="checkbox"/> PROC. <input type="checkbox"/> SUPPLIER <input type="checkbox"/> OTHER:							
RESPONSIBLE AREA (EXPLAIN CORRECTIVE ACTION)							
CORR. ACTION SIGNOFF:		DATE EFFECTIVE		ASSIGNED FOR FOLLOW UP			

Q-18

FIGURE 2

MACHINING JOB CHEC

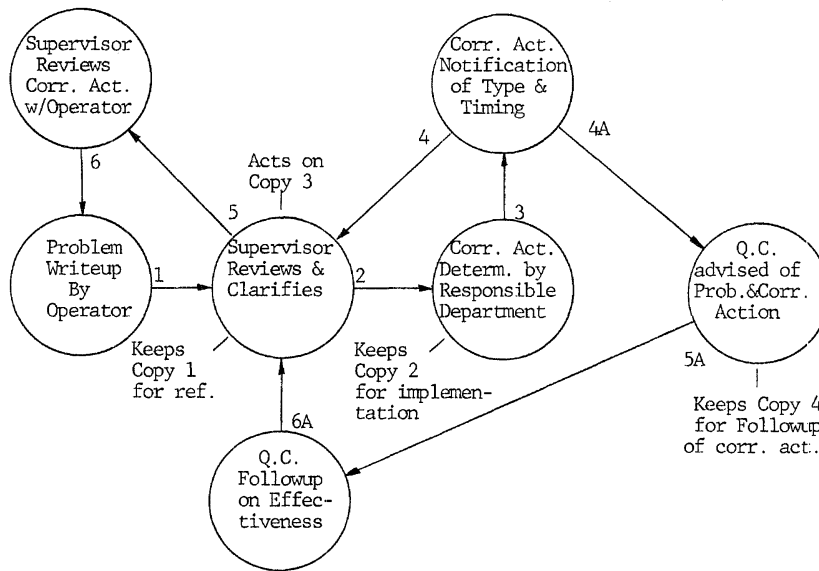


PRINT/PROCESS REVIEW		MACHINE REVIEW	
•Blueprint Correct & Clear	•Information Adequate	•Correct Speed	•Correct Horizontal Setting
•Process Correct	•Unknowns / Problems	•Correct Feed	•Machine Functioning OK
•Process= Print	•Areas to Machine	•Correct Vertical Setting	•Machine Capable
TOOLS/FIXTURES/LOCATION REVIEW		MATERIAL/PARTS REVIEW	
•Tools Correct & Sharp	•Inspection Tools	•Correct Material	•Correct Prior Operations
•Correct Fixture	•Locating Surfaces OK	•Correct Size & Shape	•Part Complete
•Fixture Capable, Complete	•Holding Method for Machining	•Material Condition OK	•Appearance OK
1st PIECE SAMPLE CHECK		IN PROCESS SAMPLE CHECK	
•Part to Print	•Part Damage	•Part to Print	•Part Moving Location
•Part Usable	•Machining Acceptable	•Machine Drifting	•Machine Settings OK
•Off Specifications OK'd	•Appearance Acceptable	•Tool Dull	•Every 10th Piece OK

E. J. Buska Printing

Q-10 10/77

FIGURE 1



SYSTEM IMPLEMENTATION

Prior to introducing the system to the operators, a foremen's supper meeting was called and the system was explained and questions and comments covered. Slogan banners using the logo enlarged were designed carrying slogans such as: "Job Check helps do it right" and "Job Check for 1st go OK". The banners were hung immediately before the meetings with the operators. All direct hourly people on all shifts attended with their supervisors. All Manufacturing Engineers dealing with floor problems were given their own meeting.

The operator meetings, held in a conference room, were all alike in format, lasted 20-30 minutes and covered the following points:

- 1) System need, explanation and benefit.
- 2) Function of the forms, routing and feedback.
- 3) Operator's roll.
- 4) Directions for filling out Problem Report.
- 5) Question and answer session
- 6) Appeal to participate for the benefit of all.

A 99% favorable response was received from the operators. A pledge was made to the operators that management appreciated the problem input and it would see that positive and timely response was made. It was pointed out the operator had to make the effort to start the ball rolling.

THE FUTURE

Plans are in the development stage to provide motivational citations and commendation awards to the operator for program participation. Shoulderpatches showing the company name with a large blowup of the Job Check man in the center with the words "Job Check Award" emblazoned around the periphery were designed for an approximate cost of 75 cents each. Automatic pencils monogrammed with the company and program logo

could be procured for about \$1.50. Other awards included credit certificates for purchase of shop tools through the company on discount.

The plan was based upon the total number of legitimate problem reports turned in over a quarter. The first five awarded the operator a patch, 10 a pencil, 20 a certificate for \$20 towards purchase of tools and each report over 20 added one dollar to the certificate value.

Commendation certificates and awards would then be awarded to all eligible operators at a quarterly supper in their honor by the plant and/or division manager. This event would be covered by the local press and in-house newsletter.

SUMMARY

The Job Check system provides a job shop process control technique to help plan jobs and reduce errors by checking job input and operator interface. Minimum job performance is specified more clearly and variation between operators is reduced. It provides a training aid for new operators.

The system also provides a problem report which can be routed for corrective action and feedback to the originating department. It then becomes a permanent record file of problems for both the "detecting" as well as the "causing" departments. The followup assignment and effective date make it simple to seek improved effectiveness and timeliness of corrective action as well as the overall performance of service departments.

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LCS 720:20:439

PARTS CONTROL
A MANAGEMENT TOOL FOR QUALITY

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INTRODUCTION

Military standard MIL-STD-965, Parts Control Program, which was issued 15 April 1977, introduces two parts control procedures -- Procedure I and Procedure II. They are intended to reduce the proliferation of parts into the military inventory, thus reducing the costs of logistic support. An equally significant benefit, however, is their contribution to the quality of the system or equipment being designed. Engineering design managers and quality managers should consider the advantages of using the parts control program as a management tool for quality.

The procedures offer two different management techniques with each one capable of being tailored to meet the needs of a particular contract. Procedure I as a general rule will be applied to most contracts, whereas Procedure II with its parts control board (PCB) concept normally will be used on systems contracts only.

Although the program controls standard as well as nonstandard parts, the part approval procedures have been simplified over past procedures by the introduction of a Program Parts Selection List (PPSL). The PPSL more clearly identifies the parts that are approved for design selection than did previous procedures, and should overcome the problems associated with identifying standard parts.

Further, the program is compatible with the current emphasis on using commercial parts, and offers many other cost avoidance features.

MIL-STD-965 EVOLUTION

The requirement for the MIL-STD-965 program evolved over a period of more than 20 years. In 1957, the results of a study on reliability were reported by the Advisory Group on the Reliability of Electronic Equipment, in which parts were identified as a major factor in field failures. Complying with the recommendations of the report, a task group conducted a more detailed study, and issued a Parts Specification Management Report in 1960. This report recommended up-dating parts specifications to establish measurable reliability requirements, thereby making the specification useable for design.

This recommendation was saying, in effect, "STANDARDIZE DURING DESIGN" to achieve quality and reliability. Subsequent studies by the Logistics Management Institute, the U.S. Air Force Panel 29, a DoD Parts System Task Group, and finally the House Subcommittee on Government Operations in two separate studies reached the same conclusion. To implement the recommendation, the Office of the Assistant Secretary of Defense for Installations and Logistics ((OASD (I&L))) directed the military departments to adopt the parts control program recommended by the DoD Task Group by 1 July 1971 for all electronic procurements.

In the meantime, the Air Force had initiated the parts control board (PCB) concept around 1967, as prescribed in MIL-STD-891 (USAF), Contractor Parts Control and Standardization Program. Under this concept, the prime contractor for a weapon system was delegated the responsibility of standardizing parts during design. This required the contractor to assure the Air Force that only those parts of acceptable quality were used. Thus, while system standardization was the primary objective of the parts control program, quality and reliability were also major considerations.

During much of the same 20-year period, a second parts control document was extensively used -- MIL-STD-749, Preparation and Submission of Data for Approval of Nonstandard Parts. While the nonstandard part approval procedures of the two documents, (MIL-STD-891 and MIL-STD-749) basically conformed to the procedures of MIL-STD-749, other standards, specifications, and contract exhibits introduced variations.

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As of January 1978, 35 different documents have been identified. The effect of the varying procedures was to cause variations in the quality of parts used in design.

Along with the different procedures, the nonstandard part approvals varied greatly. A contractor might receive approval for a part from one procuring activity, but have the same part disapproved by another procuring activity. This is understandable when the different kinds of applications are considered. A part which is acceptable for an environmentally controlled ground site may not be acceptable in an aircraft which subjects the part to different environments and stresses. From a quality and standardization aspect, however, parts used in similar applications should have been approved regardless of the procuring office making the evaluation.

When the OASD (I&L) order was given in 1971 to apply parts control to all electronic systems contracts, the Defense Electronics Supply Center (DESC) was assigned the task of reviewing nonstandard parts for the Army and Navy. (DESC had been conducting such a review for the Air Force for several years under an agreement between Air Force and the Defense Logistics Agency.) In this review, it was determined that more than 50 percent of the nonstandard parts proposed by contractors were more than adequately covered by military specifications. In most cases, the parts were not equal to the quality of the specification parts, and in only a few instances did contractors attempt to justify the parts on the basis of quality. The usual justification was "no standard part available," meaning, of course, that no standard part existed exactly like the nonstandard parts.

Moreover, some designers mistakenly believed that any part covered by a military specification was "standard." Or, that any part which was "standard" to industry was also "standard" for a military contract. Thus, many so-called standard parts were used without approval of the procuring activity, even though they did not measure up to expected quality requirements. This situation was discovered during the review of parts used under MIL-STD-891(USAF).

System standardization was accomplished under MIL-STD-891(USAF) by listing parts in a PPSL, which was divided into a Standard Parts Section and a Limited Application Section. Of the so-called "standard parts" proposed for listing, approximately 23 percent were obsolete, or their quality characteristics were inadequate to meet contractual requirements.⁽¹⁾ In these cases, the parts had been selected from military specifications, and had been chosen on the basis of lower costs. Sometimes the contractors were exhausting stocks used on previous contracts. Such decisions may be economically justifiable to contractors, but the lower quality equipment increases the life cycle costs, and these costs more than offset the savings.

Another contributing factor to properly identifying standard parts was the variety of meanings for the term "standard part" as used within the Department of Defense. Although recent changes have clarified the term, it was possible to have parts which were "standard" for design, parts which were "standard" for production, and parts which were "standard" for supply and maintenance, all with different criteria and implications.⁽²⁾ Recognizing the difficulty in a universal definition, MIL-STD-749 left the criteria to the governing general military equipment specification, or contract.

Even MIL-STD-891(USAF) complicated the definition. In this use of the term, any part which was acceptable for design application throughout the entire system was "standard" for the system. Once the part was listed as "standard" it could be used without further justification, even though it might be a commercial part. Parts control in this sense was intended to standardize parts within a system.

After more than 10 years of acquiring data on the quality of parts used in design, and after seeing the problems created by the existence of so many parts approval documents, the decision was made to establish a single parts control program, and to issue MIL-STD-965 with controls for both standard and nonstandard parts. Further, experience with logistics and quality problems on other parts such as fasteners mandated expanding parts control to include all parts -- not just electrical and electronic parts.

In a point not related to quality, but one which is important to understanding the subject, clarification should be made about the term "all parts." MIL-STD-965 excludes structural members and machined parts that are specifically fabricated for a particular application, and are not adaptable to other applications. Thus, for example, a bracket made to mount a card assembly is exempt from the parts control program.

The problems associated with the definition for standard parts has been resolved in MIL-STD-965 by renaming the two sections of the PPSL. Section I is titled "General Application Parts" which allows any part to be listed regardless of whether its origin is from the commercial field, or from a military specification. This title is consistent with the intent of the section, and likewise is consistent with the title of the second section, "Limited Application Parts."

Another significant change has taken place in MIL-STD-965 from previous parts approval procedures. Contractors are encouraged to call Military Parts Control Advisory Group (MPCAG) engineers at the Defense Industrial Supply Center (DISC) and DESC to discuss parts requirements. This procedure has been effective for some time in reducing the number of nonstandard part submittals, and has improved the quality of parts being used in design.

More significantly, engineers now communicate with one another about the characteristics of parts, and about problems that might be encountered with some parts. The designer now has more information in enabling a decision to (1) design around the deficiencies, (2) specify quality requirements in part procurement specifications that will assure receiving acceptable parts, or (3) select other parts.

QUALITY/PARTS CONTROL CASE HISTORIES

Historically it has been argued that any standardization activity such as parts control detracts from quality and reliability. The following case histories are offered as evidence that parts control can contribute to quality, and help avoid costly system or equipment down-times, production costs, and field maintenance costs.

In a research of reliability and its impact on life cycle cost (LCC), conclusions were reached that the LCC objectives can best be met by standardizing parts, provided the appropriate parts are used. Two of the radars under study were similar in acquisition cost with the APQ-120 at \$24.2M, and the APQ-113 costing \$17.1M. The spares acquisition costs were higher for the APQ-113, but the monthly logistics and maintenance costs were \$299 for the APQ-113 compared to \$746 for the APQ-120. These monthly costs represent a differential of 2.5:1.⁽³⁾

The report shows the APQ-120 demonstrating a 4.3-hours MTBF, or 50 percent of its requirement, while the APQ-113 exceeded its requirement by 12 percent with a demonstrated 152-hours MTBF.⁽⁴⁾ The number of parts used in the APQ-113 were limited to approximately 10,700 parts, whereas the APQ-120 used 13,500 parts.⁽⁵⁾

The report concluded that standardization using the wrong parts adversely affected reliability. The APQ-120 standardized on military specification parts, but the parts were being superseded by established reliability (ER) parts. (The contracts were in effect during the period when the conventional parts specifications and the ER specifications were both listed in the military bookform standards. Both kinds of parts were considered standard.) The report recommended that all parts should be screened to a reliability requirement such as testing extra (TX), ER, or to the new general specification for microcircuits, MIL-M-38510.⁽⁶⁾

A second example shows that unwarranted costs are incurred during production if substandard quality parts are used. In an analysis of failures of microcircuits used in two F-15 aircraft equipment, McDonnell Douglas Aircraft Company reported the removal rate of microcircuits in card assemblies was 2.7 times greater for nonstandard than standard MIL-M-38510 microcircuits.⁽⁷⁾ The major reasons for the difference in quality were attributed to the less stringent vendor catalog test conditions, and the closer vendor surveillance by government inspectors for the MIL-M-38510 microcircuit procurements.

While no production repair costs were cited in the report, they could be significant when you consider that 13,465 nonstandard microcircuits were processed through manufacturing during the 12-month study period.⁽⁸⁾

This final example compares before and after standardization of a navigation system. In the system produced without a formal parts control program, more than 250 part types were used in design. These types represented a population of 4000 parts. The reliability record of the system was excellent demonstrating 1139-hours MTBF against a predicted 1190-hours MTBF.

Under an Air Force contract a new version of the system was developed. The contract imposed a formal parts control program, and set a goal of no more than 3700 part

population. The completed system improved on the goal by 16.8 percent with a part population of only 3077 parts. Although no goal was set for the number of part types, the system used only 183, thereby improving by 26.8 percent over the nonstandardized system.

The contractor was apprehensive at the outset of the contract about the effect of parts control on reliability. Nevertheless, management control was exercised and 87 percent standardization was achieved. The 13 percent nonstandard parts were mostly microcircuits not covered by MIL-M-38510. The parts control program paid off when the reliability demonstration exceeded expectations. So few relevant failures were recorded during the first 644 hours of test that the demonstrated MTBF should easily exceed the predicted 1474-hours MTBF.

COST AVOIDANCES

Although the scope of the parts control program covers a broad range of parts, MIL-STD-965 provides many cost avoidance features that should make the program very attractive to a quality manager. Foremost is the provision that permits tailoring of the procedures to meet the objectives of the procuring office. Thus, for example, parts that do not impact quality and reliability can be exempted from control on a specific contract.

Responsiveness to contract schedules is another cost avoidance aspect not present in previous parts approval programs. Telephone contacts between parts engineers has already been cited as one method of expediting replies. When a written submittal of a nonstandard part request is required, the procuring office is obligated to reply within a time schedule established by the contract. If the reply is not received the part is automatically approved. Many procuring offices have adopted the practice of replying only when disapproving parts.

A third cost avoidance feature is associated with the telephonic procedure. Under Procedure I, parts requests normally will be handled by telephone with the MPCAG at DESC, or at the DISC. The MPCAG will confirm its recommendation in writing to the contractor, and to the procuring office. This procedure eliminates a cost to the contractor for each submission. Even the need to confirm a nonstandard part request is eliminated when agreement is reached to use a standard part.

Additional reduction in documentation costs accrue from a significant reduction in drawing requirements. A drawing will be prepared only when a part is selected for design from an approved PPSL. This precludes preparing a drawing that has less than 50 percent chance of being approved. (More than 50 percent of the nonstandard part requests are disapproved.) With drawing costs ranging from \$500 to \$9000 each, and with 11,676 nonstandard part requests being disapproved at DESC alone in FY1977, this conservatively avoids more than \$6.5M for electrical and electronic parts drawings.⁽⁹⁾

Field maintenance of failed equipment represents a cost that can be reduced through parts control. According to one study, the cost of field maintenance ranges from \$225 to \$408 for each action, at an annual maintenance cost amounting to \$6.1 billion.⁽¹⁰⁾ With maintenance costs averaging more than \$300, improved quality through parts control could significantly reduce the maintenance budget.

COMMERCIAL/MILITARY PART QUALITY

You may have observed that the parts control program seems to be on a collision course with the drive for increased use of commercial parts. However, as has already been stated, MIL-STD-965 allows for the use of commercial parts. No conflict should exist between the objectives of the parts control program and the objectives of the Government agencies advocating the use of commercial parts. How well the conflict is avoided is dependent upon how effectively quality control becomes involved in the part selection decision process. From my vantage point as a quality control consultant and as a standardization consultant, quality control must participate in the decision making to assure consideration of the long-term effects of the decision.

Expanded use of commercial parts is advocated in the Government on the basis that military specifications tend to apply the same criterion to all applications. "Gold-plating," "overkill" and "cost-drivers" are some of the terms given to the specification requirements, and in some cases appropriately so. However, careful consideration must be given to the impact of reducing quality requirements. For example, a recent paper cited high reliability electronic parts as being unnecessary for an attended ground radar system. The author stated the difference between commercial and military microcircuits as being in the screening and burn-in done to eliminate the imperfect

devices that slip through the manufacturing process. It was suggested that the system could do its own screening, and the better quality military microcircuits could be used in repair. It was further suggested that the increased failure rate might even provide a better training experience for a maintenance crew.⁽¹¹⁾

Screening and burn-in do contribute to the better quality of the military microcircuits, but these are not the major factors. The military microcircuits are subjected to rigorous process control, tighter electrical parameters are specified, and the devices are inspected under tighter test conditions.

Perhaps the suggestion about increased failure rates giving maintenance crews better training was made with tongue-in-cheek. However, such a concept would be extremely costly, and would result in increased system down-time. Consider an airport radar with a 10,000 part population, and having a two-percent failure rate. That radar would be out of service on at least 200 occasions, and at \$300 for each repair the maintenance costs would approximate \$60,000. This is an exorbitant training cost, but more significantly the system could be out of operation 66 percent of the first year of operation.

Commercial parts in such an application do not seem to be the logical choice. However, waiver of some quality requirements of the military microcircuit specifications for this application might be appropriate, and could reduce costs. The high altitude requirement might be one such requirement. These are the kinds of decisions that, in my judgment, must be made to assure that commercial parts are used when appropriate. Quality should not be sacrificed on the altar of cost savings.

CONCLUSION

The premise that parts control contributes to equipment or system design is more than substantiated by data accumulated in the 10 years prior to issuing MIL-STD-965. Standardization does not inhibit technological advance when applied properly, and the tailoring permitted by MIL-STD-965 gives designers wide latitude for selecting quality parts.

Significant cost avoidances are achievable under a properly managed parts control program, with a major portion of the benefits being in reduced field maintenance cost. Such a potential merits the attention of the quality control manager, and removes parts control from the sole realm of the standardization manager.

LCS 342:70:991

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NO FAULT SCRAP AND REWORK ACCOUNTING

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To the Accountant, reporting scrap and rework is obvious and straight-forward but to those who must make those charges the fear of blame and the uncertainty of repercussions can send a shudder down the spine. As a result when conventional approaches are used, scrap and rework charges go underground. My investigation of this subject in several companies indicated that scrap and rework is at least as much an emotional problem as it is an accounting one. No matter who is involved, foreman, supervisor or manager, the question is always asked - "where shall I charge this scrap?" When what is really meant is - "how can I make this problem go away without hurting me." I have uncovered a number of ploys which are in current vogue.

1. Charge the scrap to a general ledger account - they are always hard to track and one more small transaction is sure to get lost.
2. Ignore the charge and eventually the accountants will have to write it off to balance the books.
3. Charge a non-existing account - by the time the "bookies" unravel it they won't know what to do - and if we're caught, we can always plead ignorance - they would believe that.
4. Charge it to the job - while the cost ratio on this job may be poor, in the long run it will average out.
5. Charge it to another job in process - that is almost impossible to detect.

There are other more ingenious schemes too - but they all have one thing in common and that is - no understanding of the objectives that need to be served by a reliable record of scrap and rework. The answer is not to detect or foil the schemes because for every one blocked, the men in the trenches will develop a new one just a little more difficult to detect. This will lead to a series of games to see just who can outsmart who. The loser will be the Corporation without adequate data to recognize and correct its management problems. It will result in poor quality products and keep the company from measuring its progress along the path to excellence.

The objective of reporting, collecting and analyzing scrap and rework costs is to be able to recognize specific high and recurring costs. By "Paretoizing" this data we are able to measure the magnitude and trends of the situation and to use our limited resources for corrective action where it will do the most good. It is truly amazing to me how much interest there is in scrap and rework costs and how many points of view can be exposed when you attempt to change the reporting situation. The accounts, the manufacturers, and the quality controllers, each have their own opinion, they each recognize the importance of the control of scrap and rework, but will be quite cautious about upsetting the existing norm, whatever that is.

The accountants interest is primarily financial, they will favor action which will reduce this cost but will have to be persuaded that it is worthwhile before they will be willing to change their accounting system.

The manufacturing interest is defensive, while they too would like to reduce the cost of scrap and rework, they have in the past, been blamed for all of it regardless of the cause, i.e., design, material, storage protection, practices, as well for those causes over which they do exercise control.

While all accounting systems must collect the cost of scrap and rework to balance the books, unless the quality interest has been considered in that system design, the data may not be in a format which can be used to get clear visibility on this important problem. The problem quality managers face is developing and selling a system which will accommodate all interests without compromise, and that is where the "No-Fault" concept comes into play.

The "No-Fault" concept is as follows:

1. Charge all scrap and rework to accounts for which Q.A. is responsible.
2. The data should be coded to indicate where scrap and rework are identified (not who is responsible).
3. Analyze the data to give the important specific parts visibility so that effective corrective action cycles can be implemented.
4. Give credit to those who find the cause and solve the important scrap and rework problems.

The whole concept is a positive way of dealing with a reality. Scrap and rework data have already cost the corporation once. The positive attitude toward it opens up an opportunity to improve. It allows management to manage and control the number of times we live through the same mistake. Quality managers and their superiors may wince at having all of the corporation's scrap and rework charged to quality, but recognize these important facts:-

1. The costs of scrap and rework have already been incurred by the corporation and it must be charged somewhere, i.e., the cost to the corporation has not changed, it's just been redistributed.
2. Scrap and rework is probably the richest vein or the quality control "gold mine" and in charging it to "quality" you have given it to a party with a vested interest in reducing that cost.
3. Charging all the corporation's scrap and rework in one place with adequate coding, gives visibility to the real magnitude of the situation and quality control the ability to generate many different actions to identify what would otherwise be hidden knowledge of its true operation.

In my first application of "No-Fault" scrap and rework accounting, I dealt with scrap and rework generated in inventory orders. It was easy to identify three basic sources of that cost.

1. Scrap and rework due to material rejected by inspection.
2. Scrap and rework caused by defective material supplied on an inventory order.
3. Scrap and rework generated when material is found defective in stores.

These three broad but simple categories gave a very quick first cut to classify our data and identify the basic causes of why scrap and rework occurred.

The same kind of basic classifications can be developed for other forms of manufacturing orders, i.e., customer orders, tool orders, purchased material orders.

It should be recognized that in developing an accounting system for scrap and rework, care should be taken in developing interface between quality, manufacturing, accounting, and the material management system. Remember that you do have an interest in those transactions which return material to stores, with those transactions which dispose of materials, for those transactions which charge time for correcting work, in effect for all of the charges that are beyond the standard cost envisioned when the job was engineered.

Provision must be made for issuing additional material to perform rework for repair and for returning good material to their inventories as appropriate. I will not spend time in this paper discussing the developments of forms and formats

for each accounting and manufacturing system has already been tailored to the products and processes germane to its products. My point here is that coordination is necessary before the fact to set up the formats, to set up the forms, to agree on the transactional tracks and to develop supporting procedures instead of arguing over who is at fault for the high cost of scrap and rework.

The whole thesis and concept of the "No-Fault" scrap and rework program described in this paper is to recognize that no good can come to the corporation by placing blame - and only by providing the non-emotional "No-Fault" type of system, can scrap and rework data flow freely into management documents that allow for effective corrective action - the best utilization for that high price already paid.

LCS 680:10:400

ULTRA SMALL DIAMETER BORESCOPIES

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INTRODUCTION

Rigid borescopes using conventional lens systems are generally adequate from the 10mm to 4mm outside diameter sizes, but image quality and brightness decrease significantly when small diameter access ports require very thin borescopes.

New developments in fiberoptic technology now make possible high quality rigid borescopes to meet such requirements.

THE SELFOSCOPE

Regarded as the smallest fiberoptic rigid borescope currently available, the Selfoscope is equipped with a stainless steel optical insertion tube of only 1.7mm (.067") in diameter. Working length models are either 110mm (4") or 176mm (6.9").

The Selfoscope has a deep depth of field from 1mm to infinity and is ideally suited for close-up observation in a small cavity. The magnification factor at 1mm (.04") is 30x; at 25 mm (1"), 1:1.

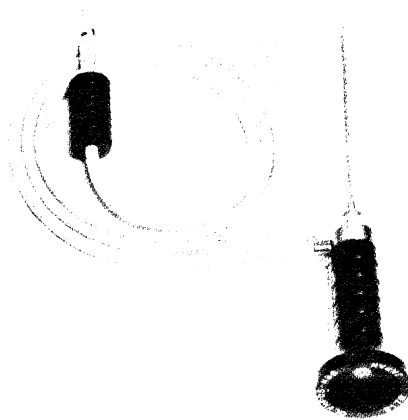


FIGURE 1.
THE SELFOSCOPE

Image Transmission

Clear resolution is obtained by transmitting the image through a single SELFOC fiber which is less than 1mm in diameter. The SELFOC[®] fiber, jointly developed and manufactured by Nippon Sheet Glass Company, Ltd. and Nippon Electric Company, Ltd. of Japan, is a uniquely formulated glass fiber with diffused metallic ions. The result is a graded index fiber; its index of refraction decreases radially from the center to the periphery according to a parabolic equation. This newly developed wide-angle, single rod lens is coated with a layer of light carrying fibers for illumination.

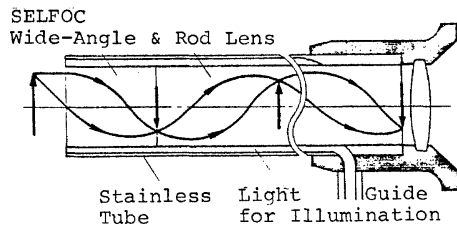


FIGURE 2.
IMAGE TRANSMISSION

Illumination

The light guide is constructed with continuous fibers from the distal tip of the scope to the external 150W, high intensity, cold light source. This continuous construction of the light guide is a critical illumination factor in a borescope of such small diameter. If the light guide was a separate and detachable unit, illumination would be reduced approximately 50% due to losses at the connection interface. Since the light guide fibers surround the objective lens, maximum illumination is focused on the viewing area.

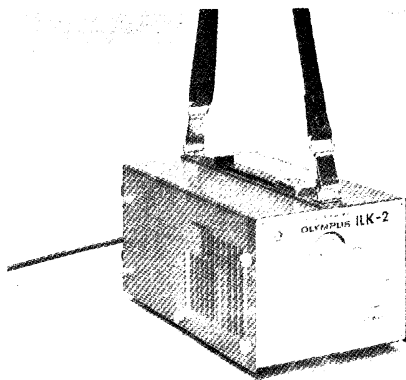


FIGURE 3.
REMOTE COLD LIGHT SOURCE

[®] SELFOC is a registered trade mark.

Direction of View

The Selfoscope's direction of view is either direct, or side, or forward-oblique. Both the direct and side viewing models have a 55° angle of view; whereas, the forward-oblique model has an angle of view of 75°.

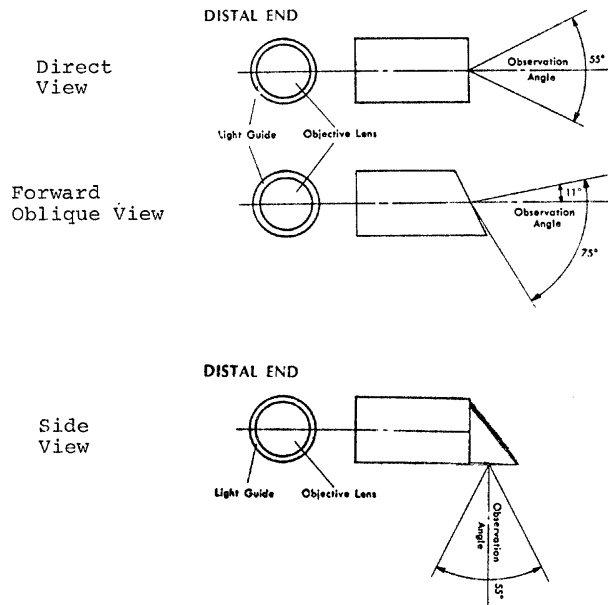


FIGURE 4.
SELFOSCOPE VIEWING MODELS

Photographic Capability

For photographic capability, a SLR 35mm automatic exposure camera is attached to the Selfoscope via an adapter. No camera lens is required since the optics within the Selfoscope are utilized for maximum photographic results.

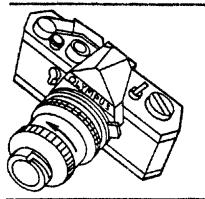


FIGURE 5.
SLR 35MM AUTOMATIC EXPOSURE CAMERA (BODY ONLY)
WITH ADAPTER ATTACHED.

Similarly, the Selfoscope may be attached to a CCTV system for magnified viewing on a monitor.

Applications

The Selfoscope is gaining wide acceptance in the quality control departments of the electronic, drug, scientific instrumentation, small motor, valve and investment castings industries. For example, visual inspections are now accomplished inside turbine blades with the Selfoscope, checking for cracks or other defects of a critical nature. This type of inspection can not be easily accomplished with other NDT methods such as x-ray; the intricate, internal construction of the turbine blading may interfere with a true reading.

Further, the Selfoscope solved a critical drive-belt mechanism problem for a quality control department in the vacuum cleaner industry. Not discovered until after final assembly, the problem was to find out which of the drive-belt mechanisms in several thousand vacuum cleaner units shipped to the field were faulty without expensive and time consuming call-back and tear-down. The simple removal of a 5/64 set screw in the housing allowed the insertion of the Selfoscope which zeroed-in to the problem area. As a result, the entire lot was inspected in the field in two days with only a very small percentage of the units subject to re-call.

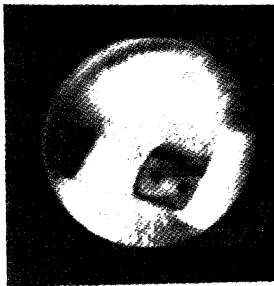


FIGURE 6.
View inside a Turbine Blade.
Photo shows the Selfoscope's
great depth of field:
separators in the foreground
the honeycomb in the back-
ground.



FIGURE 7.
View of a Circuit Board
Inside a Housing.
Photo shows the Selfoscope's
magnifying capability.

CONCLUSION

Visual inspections inside very small cavities with the Selfoscope are fast, simple and inexpensive in comparison with other NDT methods.

In this age of miniaturization, a finished product may be so compact that a quality control inspection of its internal components is difficult. The solution to this type of problem may very well be the ultra small diameter Selfoscope.

LCS: 750 70 438

QUALITY AUDITS IN SUPPORT OF SMALL BUSINESS

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University of Manitoba

INTRODUCTION

The Quality Control Handbook (1) states: "Because standards for audits are still in a state of evolution the written material is not complete and there remain important unanswered questions."

One of these questions concerns quality audits for small, independent enterprises. This paper deals with an innovative audit service especially designed for small business.

BACKGROUND

Inadequate planning and control of operations ranks as a major cause for small business failures. This critically weak management extends to quality control. Many owner/managers do not consider quality of design, conformance and performance an issue that urgently requires their attention. In a prevailing environment of informality and personal relationship one still assumes "good workmanship" sufficient for assuring quality, although often it remains undefined and therefore uncontrollable. Technological advances along with other socio-economic changes have changed needs and conditions for quality control in small enterprises drastically.

One cannot expect that small business will improve its quality control without aids from the community. In realization of the importance of a healthy and competitive small business section in a free enterprise economy various kinds of management assistance programs already exist. The Small Business Administration (2), as the best known supporting agency, for instance, has helped effectively. In the area of improving quality control, however, the available assistance is minimal, mainly because small business operators do not perceive the need to, and the benefit of modern methods. For outsiders, free enterprise principle do not allow undue interference with management. Still, in this case initiative had to come from elsewhere than the small business; at least in Manitoba.

Quality audits appeared to us as a feasible and useful external aid to small business management. Before designing a suitable audit service we explored the following questions:

- What is a workable definition of 'small business' and what is its scope?
- What are unique features of quality control in small business?
- What are the limitations of current quality audits in small business as a guide for management?

SBA defines "small business" as "firms which are profit seeking, have 500 and fewer employees and are not dominant in their field." 97 percent of all U.S. companies fall into this category (3).

In recent years growing importance of quality control in small enterprises arose from the following:

- technology related to products, processes and equipment has become more complex and demanding to producer and consumer.
- customers require compliance with generic standards for quality control programs.
- other small companies have already established effective quality control procedures and gained competitive advantage.

- legislation for consumer protection, higher incidence of product liability claims and reduced rates for insurance require evidence of an adequate quality control program.

A manager/owner finds little help from his traditional management advisor, the accountant, with regard to quality control. Quality auditors that represent government and customers' interest cannot act freely and independently. These quality audits are for the small business operator of limited value by the following reasons:

- main purpose of the audit is to establish evidence and to attest rather than to assist,
- they are not requested by the owner/manager in awareness of need for and possible benefits from improved quality control. The audits are more or less imposed upon them.
- they are conducted infrequently, in conjunction with a specific contract or legal act, and without due regard to small business conditions.

THE PROBLEM AND STRATEGY

On one hand, mounting pressures for improved quality control and insufficient service on the other caught small business in the middle. It became obvious that the main problem rests with the owner/managers in that they are reluctant to act, and to initiate assistance. In order to overcome this mainly psychological problem we proceeded very cautiously (4). In our strategy and audit service we remain cognizant of the following characteristics of typical owner/managers of small enterprises:

- they tend to operate by "common sense", tradition, trial and error and day to day problems. They are not professional managers.
- they are hard working, self-reliant and energetic individuals and do not accept advice from outsiders easily.
- they maintain close personal relationships with employees, business partners and the surrounding local community.

With this personality in mind we arrived at a strategy by which we approach owner/managers first on a community wide basis and later individually. A "community quality audit" precedes and prepares "small company audits". Figure 1 shows a design of a comprehensive quality audit service with two interlinked sub-types that is geared to take advantage of close relationships between community and small business. In this scheme owner/managers hold a central position as an active and decisive participant in the quality audit.

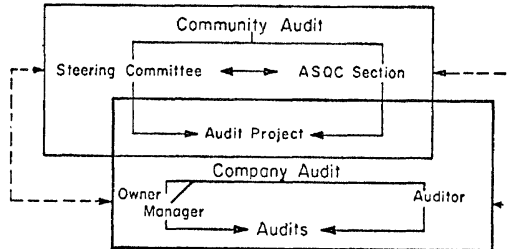


Fig. 1. Quality Audits at Community and Company Basis

COMMUNITY QUALITY AUDIT

Main purpose and objectives of this new kind of quality audit are as follows:

- generate information on the status quo of quality control, scope for improvement, need for assistance and availability of resources,
- create an awareness for quality control in the community and its small business section,
- establish first contacts with small business operators and explore the clientel for company quality audits,
- conduct research and provide a report for a steering committee.

An initial base-line audit explores the status-quo on a limited scale and in general terms, provides learning experience for auditors and auditees and creates interest and further support in the community at large. A standard for subsequent community audits in form of an expected and desirable status of quality control in the community will gradually evolve with time.

Community quality audits constitute "audits" and not just "surveys" because they aim at:

- establishing a general standard for a community wide quality program and quality control improvement program,
- appraising and improving the effectiveness on such programs,
- implementing the policies of the steering committee,
- ensuring that human, financial and material resources are adequately known, utilized, and developed,
- initiating remedial action and follow-up audits at both community and company levels.

With regard to the classification of quality audits by Mills (5) community quality audits describe a location and system oriented audit rather than a product and process audit.

Who should initiate such community quality audits? This responsibility will fall on the steering committee. This committee should have a strong representation from small business. While government officials will not qualify as independent auditors they can contribute as committee members along with those of other organizations.

The baseline audit sets the stage for the entire audit program. Actually, anybody sufficiently motivated, informed and able to attain the cooperation of others can pioneer such an audit in the local community. The author, being involved in the local quality movement for some years as educator and executive members in the ASQC Section of Manitoba originated the first community quality audit. The Manitoba government had conducted similar so-called Productivity Audits and joined in the project along with individuals from the university, ASQC and other local organizations. A faculty member of the local university has particular advantages to act as "neutral" leader.--In the U.S. such audits qualify for grants under Bill S-972 for Small Business Development centers at universities.--

In our Manitoba audit we applied a fairly conventional approach. We used questionnaires and question checklists. Of 700 small manufacturing establishments, about 40 percent responded. We checked a great number through subsequent interviews. These we carefully prepared as we wanted not only to gather data, but at the same time establish first personal contact with a hopeful future client for a company quality audit. With the exception of the initially mailed questionnaire the procedure compares with that of a normal company audit.

We tabulated the answers and statistically evaluated them for proper analysis. Most interesting and revealing were also answers to our open questions. It became quite clear that many of our owner/ managers recognize the importance of improved quality control. They want better training opportunities and information service in order to overcome quality control problems. With regard to company quality audits many were prepared to submit their current practices to an appraisal and as a prerequisite for improvement. These audits, however, were to be conducted by an independent, well qualified auditor, who is neither employed by another company nor the government. At the end of the community quality audit we knew our potential clientel for company quality audits quite well.

A report on the community quality audit we forwarded to persons in local associations, government departments and educational institutions along with a request to join a steering committee. All of them responded enthusiastically, somewhat to our surprise. This showed that at least in our province quality control is an issue very much on the mind of many people. This independent "citizen committee" elected the author as its chairman and provided a well appreciated and unique forum for discussing concerns for better quality control in the business section of the local community. With focus on improvement of quality control the committee developed its function and role as a policy making and management body. (See figure 2.)

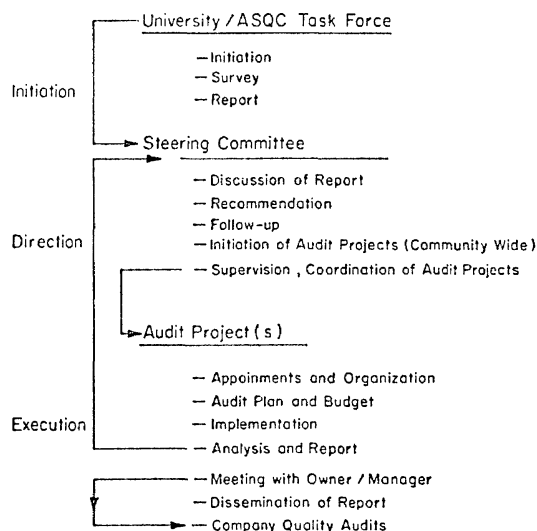


Fig. 2. Community Quality Audit

The report from the community quality audit provided the major basis for discussion and constructive recommendations. As a result of the partly quite demanding work of the committee a government position for a coordinator of quality assurance has been created, a university certificate course in quality assurance management arranged with a surprisingly high enrolment and finally quality audits in small companies have commenced.

SMALL COMPANY QUALITY AUDIT

As mentioned before, one of the major objectives of our community quality audit was from the outset to contact small business operators, to inform them about quality control, to actively involve them in a broadly based quality audit and thus to prompt them in their request for an independent company quality audit. What we really were looking for was a genuinely interested clientel for these audits which once satisfied with our service would induce others to follow and request the same service.

The following reasons caused owner/managers to participate in quality audits:

- through the preceding community wide project they simply wanted to continue in a project with which they identified themselves already; they continued in the effort,
- they learned from meetings and the report enough about quality control with regard to their immediate local environment in a most realistic, simple and practical manner. Naturally, they wanted to know more details about the comparison of their current company practices with the prevailing status in the surrounding local community.
- they acknowledged and appreciated the steering committee and its individual members as competent and reliable trustee for conducting and surveilling company audits and independent quality auditors.
- they became acquainted with some of the quality auditors who actively participated in the community quality audit.
- they realized that benefits will easily exceed the costs partly because public grants for the audit were made available.
- they recognized that because of the prevailing close personal ties in small business to bring about more formal and restrictive quality control procedures would be difficult without the help from a competent quality auditor as an outsider.

In more detail, owner/managers expect from this company quality audit the following service and outcome:

- an interpretation of the report on the community quality audit with regard to the individual company,
- an assessment of current quality control practices of the company and recommendations for simple, practical and short term improvements,
- an assistance in setting-up such an improved quality control program,
- a documentation of this quality control program in an easily understandable language and form, that facilitates implementation and maintenance through self-audits by the owner/manager,
- further convenient availability of the auditor whenever needed.

The owner/manager does not want an audit that completely by-passes him/her and results in a report. Obviously, a quality audit geared to assist a small business operator has different features when compared with those in large companies. The auditor of a small and independent enterprise must work very closely through all phases of the audit with the owner/manager in order to be accepted and to render useful service.

Consequently such an auditor must have acquired additional qualifications such as:

- knowledge and experience in small business management along with a sincere appreciation of small business values,
- ability to communicate well with small business operators, to listen, to understand, and to work with them rather than for them,
- competence in adopting generic program standards, specific procedures and methods to needs and conditions in small business.

Individual phases of the audit in which client and auditor have to work together are depicted in Figure 3. From the discussion of the community audit report and the owner/manager's perception of quality control in the company should emerge fairly precise expectations and goals for the audit. Such a careful preliminary orientation

Initiation	<ul style="list-style-type: none"> — Owner / Manager Request — Auditor Contacted
Planning	<ul style="list-style-type: none"> — Orientation , Objective — Audit Plan — Budget Contract
Execution	<ul style="list-style-type: none"> — Audit — Reporting — Recommendation and Documentation — Follow-up

Fig. 3 . Company Quality Audit

of both parties ensures best the owner/manager's continued interest and active participation in the audit itself. The audit is built around the owner/manager entirely. A final audit plan shows various activities and its purpose and also a time schedule that allows full participation of client and auditor. An audit plan, formulated in writing constitutes a contract that can assist also in raising financial support for the project.

In order to guide further research and development in small company quality audits we designed an audit plan as a kind of tentative standard. If the owner/manager requests a quality audit without the involvement in a preceding community audit, this company audit plan can still be applied. This standard audit for a small enterprise achieves the actual establishment of a practical and suitable quality program through the following stepwise approach:

1. determine existing quality control/inspection practices.
2. formulate these in writing in a simple language and augment with charts, etc.
3. discuss, clarify and possibly revise these current practices with owner/managers and other individuals concerned.
4. document approved practices as standard procedures in a quality manual.
5. determine voids by comparing current practices with needs and possibly suitable generic standards for quality control programs. Have owner/owner/manager decide whether additional control function and procedures are required.
6. prepare simple forms for reporting and data compilation and document these in the manual.
7. implement procedures and reporting schemes; possibly revise when necessary.
8. prepare checklists and simple plans for self-audits to be conducted by the owner/manager or an employee and include these in the manual.
9. set date for next self-audit.
10. clarify future services by the auditor and enter auditor's endorsement of the quality program in the manual.

These ten steps would have to be further extended in order to suit individual circumstances and personalities.

The standard audit plan once jointly executed provides a most valuable learning experience for both partners. Owner/managers become adequately acquainted with modern quality assurance planning and with sound management practices. The focus on learning in an extremely practical and mutually beneficial manner strikes the main difference between this small business quality audit and others. Usefulness derives

from the auditing exercise and not from a final report and recommendations.

Moreover, the tangible outcome, the quality manual, represents and documents an operational and actually implemented and hopefully proven quality program. The owner/manager him/herself has prepared this manual and it constitutes most likely a real management breakthrough. Without question, this program has every chance to be properly maintained through self-audits and improved when needs command this. The owner/ manager has become sufficiently trained in quality control directly in his company setting and at the same time has a quality program instituted with adequate evidence in form of the manual. Customers, suppliers, governments and others will share the benefit.

One major problem in implementing these quality audits lies in the unavailability of auditors. Further shared research and development by educators and practitioners will hopefully soon close the gap.

SUMMARY

This paper had to be confined to a general outline of our work in this project. Community and company quality audits together, once carried forward through cooperative efforts promise to create an invigoration of quality control at the local level. In our community we have found the concept and practice workable and useful. We help small business to help itself in building competitive strength through better quality control and ultimately to more satisfied customer and more productive business operations.

While in our audit service, initiative rests and remains with the small business operator, leadership emanates from the local university and ASQC Section. It also allows government to play a meaningful guiding and supportive role in its small business policy and programs.

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THE TRAINING & CERTIFICATION OF NUCLEAR
Q.A. AUDITORS

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INTRODUCTION

Mr. Lee Everett, President of Philadelphia Electric Company at the ASQC Nuclear Quality Assurance Conference October 1-3, 1974 made the following statement:

"Quality Assurance is at its best when it is doing an audit. The Quality Assurance Manager keeps all management informed about the information they need to know."

Auditing is, if not the most important, at least one of the most important tasks performed by Quality Assurance personnel. Dating back to the earliest use of auditing as a financial tool, it has become management's mechanism for learning about what is actually taking place and the means for detecting potential problem areas as well as a source for preventing these problems from affecting cost, schedule, quality, and or safety aspects of the job. If used properly and on a timely basis it can be the most significant means for alerting management to all types of potential trouble areas thereby both minimizing their impact and establishing a media for their solution prior to catastrophic results.

WHY AUDIT?

The conducting of an audit involves clear and objective responsibilities on the part of all concerned. With the increasing use of qualification and certification, the recommendations and actions from audits are expected to have increasing importance. A properly conducted audit is a very important aid to management. For optimum value, audits should be properly organized for: purpose, coverage, schedule and planning. Proper organization eliminates confusion and delays. Planning makes for a more efficient audit and provides the proper professional approach.

AUDITOR CERTIFICATION REQUIREMENTS

It is not necessary to spend too much time discussing this topic since it is fairly well explained in ANSI Standards N45.2.12 and N45.2.23. I would, however, like to discuss this area a little further. Some other factors should be considered such as:

1. A thorough knowledge of company policies and procedures.
2. A knowledge of the applicable codes, standards, specifications, departmental or organizational procedures is necessary as related to the specific audit being performed.
3. The ability to deal with people is a critical prerequisite.

QA AUDITOR TRAINING

Auditors, in order to be most effective, must have certain traits. A listing of those which are considered most important should help to illustrate this: Personable, inquisitive, systems oriented, objective, good planner, problem solution directed, a good researcher, good speaker and writer, ability to cope with different personalities, knows how to develop and use the art of questioning, constructive, knows how to listen, and has the ability to discern "the vital few versus the trivial many".

When we consider the need for the above mentioned characteristics we conclude that the auditor must either initially have these traits or develop them via an extensive training program. This training program therefore consists of several parts. These parts occur at varying intervals starting with an individual undergoing orientation training upon joining the company, specialized auditor training while on assignment, follow-up training, and, when required, specialty oriented training covering such areas as NDE, Welding, special processes, etc. We will examine these in the order of their occurrence. The order will be reviewed relative to time starting with preemployment requirements.

1. Pre-employment Requirements

In order to facilitate a proper evaluation of prospective auditing personnel by the Personnel Department we have developed a personnel course, titled "QA Orientation For Personnel Department". An outline of this course is illustrated as Figure 1. The Personnel Department serves as the initial screener for the basic traits required of those whom we intend to hire to perform auditing tasks. Obviously the objective of this stage is to make available those type individuals that are best qualified for development as auditors.

2. Orientation Training

A new Quality Assurance Department employee is required to undergo a period of orientation training varying from 21 to 37 days depending upon his past experience. During this period the orientee receives basic training preparing him for future auditing tasks. Some of the subjects covered are listed below:

- PSE&G QA Organization, Responsibilities and Role of Specific People
- Key Features of the QA Program
- QA Interface Relationships
- QA Requirements
- Codes and Standards
- Major Contractor QA Programs
- PSAR and FSAR
- Organizational Policies and Procedures

Included within this training period is the requirement for the new employee to perform specific tasks such as:

- Review of a QA Manual
- Prepare audit questions based on the requirements of 10CFR50, Appendix B.
- Participate in an audit
- Prepare for an audit including preparing an Audit Plan, conducting an Audit, and preparing an Audit Report
- Prepare a Procurement Control Plan

The employee's progress is continually examined and evaluated. After the orientee satisfactorily completes this training he is assigned to a specific area within the Department.

During the course of his regular activities on the job additional training is given as a part of individual technical development. This includes specific on-the-job auditor training, further classroom training, and specialty type training as required. On-the-job training involves further participation on an increasing responsibility basis for auditing. The individual's development is monitored by his supervisor. The program is developed by the department Training Engineer. Records are maintained on the individual and in the employee's personal files.

AUDITOR TRAINING

If it is judged that more detailed training is required, the individual has to participate in a special auditor course. This consists of fifteen days of continuous training encompassing three days of classroom sessions and twelve days of closely monitored on-the-job training under the direction of the Training Group. The classroom sessions involve such topics as:

- Company QA Manual
- Preparation of Audit Questions
- Use of the CASE Questionnaire
- Elements of Control
- Objectives of QA Audits
- Type of Audits
- Essential Elements of an Audit System
- When to Audit
- Audit Frequency
- Qualifications of Auditors
- Preparation for Auditing
- Notification of an Audit
- Performing the Audit
- Post-Audit Conference
- Audit Reporting
- Audit Follow-up

During the classroom sessions exercises are conducted using the technique of Role Playing presenting the trainee with simulated conditions including the various type personality traits he may meet during an audit and how he should handle each type.

The training includes detailed discussions in such areas as Auditing Techniques, Questioning Techniques, Listening Techniques, the Use of Questions and Key Words for Questions. Included also is a review of the roles people play in meetings. Copies of some of the handouts distributed and discussed are attached as Figures 2 - 4.

To further develop the abilities of the prospective auditor additional courses presented by other departments within the company are made available. Two of these courses are Report Writing and Effective Speaking. Elements included in the Report Writing course are:

- General Principles
- Types of Reports
- Outlining the Report
- Composition
- Mechanical Form of Reports

Application is included with the discussion of each topic.

The Effective Speaking course utilizes closed-circuit TV equipment. Each person must make several presentations of various content and length. Each presentation is filmed and then critiqued by all attendees. Elements of the Effective Speaking Course include:

- The need to speak effectively
- The personality of the speaker
- Presenting the talk
- Use of visual aids

SPECIALTY AUDITOR TRAINING

Specialty auditor training consists of specialized training covering such areas as NDE, Welding, ASME Codes, etc. In-house training courses, as well as courses given by outside consultants are used for these purposes developed and administered by the QA Training Group working with specialists in the applicable fields.

Individual auditor proficiency is maintained by a continuing personnel evaluation program. Each individual's performance is regularly and annually appraised to assure proficiency is maintained.

CERTIFICATION PROGRAM

Certification of auditor is formally implemented utilizing the guidelines of ANSI Standards N45.2.12 and N45.2.23. Figure 5 is a sample copy of the form used and retained in the individual's training files. Great weight is placed on the individual's demonstration of capability on the job, during annual performance evaluation. The certification program consists of two classifications, Auditor and Lead Auditor. Minimum requirements involve the attainment of a minimum of ten points.

Figure 5 illustrates the form used to document the qualifications for certification of an Auditor or Lead Auditor. The maximum number of points possible is 17, subdivided in accordance with the requirements of ANSI Standard N45.2.23 as follows:

1. A maximum of 4 points with 2 for the equivalent of an Associate Degree to 4 for a Graduate Degree in specific disciplines.
2. A maximum of 9 points based on experience in the field with emphasis on experience in nuclear QA Auditing.
3. Two points for certification of competency issued by a state agency or national professional society.
4. Two points for evaluation of competency by management.

No one is certified as a Lead Auditor until total capability is demonstrated to cover all aspects of an audit including a thorough knowledge of the applicable requirements, awareness of personality traits, and other critical details so intimately concerned with auditing.

TRAINING RECORDS

The PSE&G QA Training Group was assigned the responsibility for maintaining the QA personnel training files. This includes copies of resumes, previous qualifications, eye examination results, attendance at workshops, conferences, courses, and symposia for each individual of the QA Department. Since this is a continuing requirement, it requires follow-up. An example of this is the annual eye examination required. A tickler file is maintained alerting the training group to schedule an eye examination for a specific individual and to assure that this is accomplished.

The records also include documentation of follow-up training. Figure 6 is a typical form used to document this information and illustrates the form used to document the periodic evaluation of personnel competency. Although the form is also used for evaluation in other areas, it serves as a measure to assure maintenance of proficiency in Auditing. The individual's performance in each auditing phase is evaluated, rated, and noted. This is reviewed annually with decisions made for further action based on the results. If inadequacy is discovered the individual undergoes additional training in his weak areas.

SUMMARY

A great deal more can be written about this subject. Discussing in greater detail such subjects as Key Control Tasks pertinent to a commercial nuclear generating station, the Quality Audit Cycle, Psychology of Auditing are also important elements which deserve examination. Books have been written on Auditing. This paper is just an introduction and I hope it opens the door to additional presentations discussing the Auditor rather than the Audit. It is certainly obvious that there can not be a successful audit without a technically competent and capable Auditor. How we assure that he is technically competent and capable is the key objective of this paper. Auditing, properly performed, can become the most significant tool toward assuring that projects are completed within established schedules. It can become the tool for reducing costs and preventing major problems. It can only accomplish this goal if implemented properly in a timely manner by technically competent personnel.

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1. Introduction
 - 1.1 Purpose
 - 1.2 Scope of QA Program
 - 1.3 Definitions
2. History of Nuclear Power Plant QA
3. Nuclear Regulatory Commission
4. Regulatory QA Requirements
5. QA Department
 - 5.1 Organization
 - 5.2 Responsibilities
 - 5.3 Interface Relationships
6. QA Personnel Qualifications
 - 6.1 Education
 - 6.2 Experience
 - 6.3 Training
 - 6.4 Personnel Characteristics
 - 6.5 Job Requirements
 - 6.5.1 Individual
 - 6.5.2 Interrelationships
 - 6.5.3 Scope of Job
 - 6.5.4 Vital Few vs. Trivial Many

FIGURE 1

KEY WORDS FOR QUESTIONS

CLASSIFY	Demands arrangement, assembling, or grouping of facts according to some common characteristic.
COMPARE	Requires detection of the resemblance and the differences among facts.
CRITICIZE	Exacts good judgement and careful analysis.
DEFINE	Determine the boundaries of a subject and fixing of a clear meaning.
DESCRIBE	Select and portray the characteristics of a subject.
DISCUSS	Present the pros and cons of a subject and come up with arguments supporting a position.
EXPLAIN	Clarify points which obscure a subject.
ILLUSTRATE	Calls for examples to clear up a discussion.
INTERPRET	Bring out the meaning of a subject as the person responding sees it.
JUSTIFY	Show that a thing is reasonable or warranted.
OUTLINE	Indicate the main points of a subject.
REVIEW	Compels going over a subject completely and giving it a critical examination.
SUMMARIZE	Ask for the presentation of a subject in a concise and compact manner.
TRACE	Follow in detail the development or progress of some subject.
VERIFY	Exacts proof that a thing is true.

FIGURE 2

THE USES OF QUESTIONS

1. To open discussion.
2. To stimulate interest.
3. To provoke thinking.
4. To accumulate data.
5. To get individual participation.
6. To develop subject matter.
7. To determine a member's knowledge.
8. To change the trend of discussion.
9. To arrive at a conclusion.
10. To terminate or limit a discussion.

FIGURE 3

1. Remain natural.
Do not give advice, agree or disagree, criticize or interrupt.
2. Give your complete attention.
Let him know you are listening, Nod your head -- "uh huh, I see what you mean."
3. Ask about his statements.
Dig out information, invite him to tell everything. Say: "In addition to that is there anything else...?"
4. Restate his main points.
Let him hear his exact words restated by you. This prompts him to stick to the facts and to think intelligently.
5. Put his feelings into words.
State what his feelings seem to be. When he hears them voiced by you he evaluates and tempers them.
6. Get agreement.
Summarize what you have both said -- encourage him to suggest the next step or course of action.

HOW TO ASK QUESTIONS

1. No third degree.
Use questions to help the other person think -- never to degrade or to spy.
2. Ask "W" questions.
What, Why, When, Where, Who and How are the key words that will secure facts and information.
3. Ask questions that make him go deeper.
Ask for evidence, examples or explanations to discover reasons behind his thinking.
4. Ask "suppose" questions.
Introduce a new idea, break a deadlock or bring up an overlooked point with: "Suppose we...?"
5. Ask him.
To encourage others to think or to avoid committing yourself, return the question or relay it to another qualified person.
6. Ask questions that get agreement.
Offer several solutions in the form of a question.

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QA AUDITOR PERSONNEL DATA QUESTIONNAIRE

THE FOLLOWING INFORMATION IS NEEDED TO PROVIDE DATA FOR CERTIFICATION TO THE REQUIREMENTS OF QAI 2.7. PLEASE FILL IN AND RETURN TO QAD TRAINING ENGINEER. PLEASE INCLUDE A COPY OF YOUR RESUME.

1.0 NAME: _____

2.0 EDUCATION DATA:

2.1 UNDERGRAD. DEGREE _____ MAJOR _____ YEAR _____
NAME OF SCHOOL: _____
ADVANCED DEGREES _____ MAJOR _____ YEAR _____
NAME OF SCHOOL: _____

3.0 EXPERIENCE DATA:

3.1 YEARS EXPERIENCE IN ENGINEERING, MANUFACTURING, CONSTRUCTION, OPERATION
OR MAINTENANCE _____
3.2 YEARS EXPERIENCE IN NUCLEAR FIELD _____
3.3 YEARS EXPERIENCE IN Q.A. _____
3.4 YEARS EXPERIENCE IN QA AUDITING _____
3.5 YEARS EXPERIENCE IN NUCLEAR Q.A. _____
3.6 YEARS EXPERIENCE IN NUCLEAR QA AUDITING _____

4.0 PROFESSIONAL COMPETENCE DATA:

4.1 TYPE OF CERTIFICATION OF COMPETENCY IN ENGINEERING, SCIENCE OR Q.A. ISSUED AND
APPROVED BY A STATE AGENCY OR NATIONAL PROFESSIONAL SOCIETY _____

I CERTIFY THAT THE ABOVE IS TRUE AND CORRECT AND IN AGREEMENT WITH INFORMATION SUPPLIED BY
ME TO PSE&G IN EMPLOYMENT APPLICATION (EXCEPT AS NECESSARY TO UPDATE THE INFORMATION).

DATE: _____ SIGNATURE OF EMPLOYEE: _____

5.0 RIGHTS OF MANAGEMENT DATA

TOTAL POINTS

FOR EVAL- UATOR USE	
POINTS	
ASGN.	MAX.
	4
	9
	2
	2
	17

DATE: _____ CERTIFIED AS: _____

EVALUATED BY: _____

REQUIREMENTS FOR LEAD AUDITOR: 10 POINTS MIN.

FIGURE 5

TRAINEE EVALUATION

Name of Trainee:

Evaluator:

Activity Involved:

Date of Activity:

Evaluation Checklist
(Check Applicable Boxes)

	OUTSTDG	SUP.	ACCEP.	MARG.	UNSAT.
1. Preparation for Activity:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Participation in Activity:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Quality of Report:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Knowledge of Subject:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Attitude:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Interface with internal personnel:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Interface with external personnel:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Overall Evaluation:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS: _____

Date

Signature of Evaluator

FIGURE 6

THE CO-ORDINATION OF QA ASSESSMENTS AND AUDITS

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Rexdale, Ontario, Canada

Introduction

With the advent of the nuclear power station, there has been a significant increase in activity relating to safety matters, by suppliers, users and governments. To design a unit that will function effectively and safely for 30, 40 or 50 years is not easy and in order to increase the level of assurance that the design is adequate, the various components are acceptable and the installation is correct, the quality control of yesteryear has been superseded by Quality Assurance requirements.

In order to meet the various regulations which apply to nuclear applications and operations, it is now necessary for suppliers to have and operate a quality assurance program, to provide assurance that their product or service meets the requirements of the contract. Each purchaser is required to satisfy himself that the quality assurance operations of his suppliers are satisfactory. Because most suppliers are also purchasers, there is an additional need for those checks to also be carried out on their suppliers, and on their sub-suppliers....to the point where either very basic materials are involved (such as a heat of steel where further, more basic, checks are not significant) or where the parts are not critical items. It is therefore easy to see how such a requirement can affect a large number of items, and therefore a large number of companies, because of this cascade effect.

It is also typical that any one supplier sells to multiple purchasers; therefore such a supplier could be subjected to assessments by many, or all, of his customers. This is a problem, not only in duplication of work but also of differences in interpretation of the standards concerned. Herein lies both problem and opportunity.

Standards

In Canada we have a series of 4 standards; Z299.1, Quality Assurance Program Requirements, Z299.2, Quality Control Program Requirements, Z299.3, Quality Verification Program Requirements and Z299.4, Inspection Program Requirements.

The Canadian Nuclear Association originally prepared the drafts of these documents, and the scope was restricted to nuclear purchases. However, before being finalized, they were made the responsibility of a CSA Committee who broadened their scopes to be applicable to purchases by the electric power generation utilities. These standards were issued in 1975 as preliminary standards and are now being re-issued as full standards.

The Canadian Standards Association (CSA) was established in 1919 and is a non-Government, not-for-profit Association whose corporate objective is Services in Support of Standardization. It has been accredited as a Standards Writing Organization (SWO) by the Standards Council of Canada. CSA has requested recognition in the subject area of the Assurance Sciences and intends to submit the Z299 series of standards for recognition as National Standards of Canada.

The availability of 4 standards which delineate 4 levels of assurance means that a purchaser, having decided on the level required (depending on the criticality of the item) can then specify the assurance level required, clearly and easily.

The principles given in these standards are applicable to almost all products and processes but additional education will be required before this is recognized, because many of those involved with mass-produced items tend to assume that the assurance sciences are for nuclear applications, must therefore be expensive, and are neither appropriate nor applicable to non-nuclear subject matter.

Background

Suppliers to those utilities who are in nuclear power generation are required to meet the requirements of the relevant Z299 standard, usually Z299.1 or Z299.2. Both of these standards require evaluation of subcontractors and because many suppliers purchase from multiple subcontractors - and they in turn often have multiple sub-subcontractors - there is a cascade effect. Many suppliers are finding that they are being subjected to multiple audits by their customers and also having to apply audits on their suppliers who are also receiving multiple audits from their customers! We recently heard of one large contractor who was involved with over 1000 audits in a year - these included audits applied on him by his customers and by him on his subcontractors.

Recognition of this duplication of effort and the basic unacceptability of expense without a corresponding benefit has led a number of suppliers to try and find a means whereby the audit process could be made more efficient. Various trade associations as well as individual companies (suppliers, purchasers and users) have approached CSA to provide a co-ordinated management of these assessments and audits.

Initial Steps

Over this past year or so, we have had a number of requests for CSA to become involved with QA activities. Some have been from individual companies and some from trade groups. While most have been from producers, there have been enquiries from companies who supply services, and also a number of users, mostly utilities.

Consideration was given to these numerous requests and a number of small, often informal, meetings were held in order to ascertain what the prevailing situation might be and whether there was a real need. On past occasions we have been approached and asked to provide a program which has had only partisan support and we wished to assure ourselves that there was a real need before spending any significant amount of time and effort on the subject.

These discussions have satisfied us that a program for the management and consideration of assessments and audits would fill a real need, would be widely supported and - a not insignificant point - would be cost-effective. Although the preparation and installation of a QA program costs money in the initial stages, it is an investment and should be considered in the same way as any other business investment. Various companies have provided data to show that there is a significant saving to the overall quality costs when an appropriate QA program is installed. The economic arguments for the installation of a QA program are among the most persuasive ones.

Having satisfied ourselves that there was a valid need, we had to consider whether CSA could fill that need. The requirements appear to call for an independent organization which was national in its operations and was also widely recognized. It was also considered necessary for the organization to be able to do the job well - a poorly executed program would be a disservice to all concerned.

Because of our past experiences with product certification we have considerable experience in certain technical areas and, more importantly, many years of experience in managing independent, third-party programs for various manufacturing industries and our programs have been widely recognized by both the Authorities and purchasers. Because we have a considerable background in both standards writing and in the interpretation and application of standards to practical situations, to manage and co-ordinate an audit program appears to be a logical extension of our current activities.

The next step was to have detailed discussions with one trade association whose members had expressed an interest in CSA managing a QA program. After several meetings, first with their technical and later with their management representatives, it was agreed that we would run a pilot project with their members. This is now being carried out and is providing CSA with additional information and background relating to the operation of such a program. The participating companies are gaining the benefit of an independent appraisal of their documentation and operations.

Factory Assessment

One of the first steps required when executing a facility assessment is to know which level the company intends to work to, and to then review their QA manual against the relevant standard. This is carried out before any assessment of the actual operations is made.

It is preferable that the manual reflects what is actually done in the plant, rather than be a theoretical document based on the requirements of the standard. Many of the current operations and techniques already in use in the plant are often acceptable. It is usually easier for the manual to reflect what is done and then upgrade procedures and practices as necessary by a process of evolution, rather than to try and impose a theoretical document on the operation.

During this review it is necessary to decide on a number of points: is the material required by the standard included? if not, it must be added: is the material relevant to the requirements of the standard? if not, it can be ignored - provided it is not in conflict with any other parts of the manual: if it is relevant, then it is clear, complete and unambiguous? if not, it needs revision. It can therefore be readily seen that, in most cases, the preparation of a manual will be a reiterative process.

It should be noted that, although the review of the manual is easier when the manual sequence corresponds to that of the standard, it is preferable for the manual to be so arranged that those who will need to use it find it easy to use.

Although it is desirable to have a complete and acceptable manual available before a factory assessment begins, this is not always practical. For example, a review of a manual may show it has a number of points needing change, correction, expansion, or clarification. While one can wait until the manual is revised, and the subsequent review shows it to be acceptable, there are advantages to making a partial factory assessment based on the available manual: if the manual needs further work it is probable that there will also need to be some revised operating procedures and instructions, and a partial assessment enables progress to be made on both documentation and operations concurrently.

Although having a complete and acceptable manual is important, it is even more important for the operations to produce the correct results: paper is not a substitute for quality. It is during operations that the required quality is built in; the associated paperwork is only a means to the end, not the end itself.

Assessment Teams

The assessment of the facility is probably the most important part of the whole program. In order that it be executed effectively, it is planned that each team be specifically selected to include adequate and appropriate expertise for the technology involved during the assessment. This means that the team will typically include consultants having the specific expertise. They will be under the general overall control and guidance of the CSA staff man who will be both the team leader and the senior auditor.

The team leader will be responsible for the overall assessment including the management interviews, manual reviews, the direction and organization of the assessment of the facility itself, as well as the subsequent feedback and follow-ups as necessary.

Records

CSA will also act as the repository for the assessment records - the consolidated information covering manual review, the assessments and follow-ups, subsequent audits and the related records. The publication of a list of those companies who have successfully met the standard will be issued on a regular basis and will include the company identification, the level to which they have been assessed, and the product range or group covered. This list will be a Register of Companies having Assessed Capability and will be of considerable help to purchasers when selecting suppliers, because they will then have the benefit of an independent assessment without the cost of having to perform it.

Qualification Program

The initial work on assessments has been done in a limited sphere, but based on the data generated, the CSA Board of Directors have taken steps to move the pilot project toward a full program, to be phased in, on a sector by sector basis. A Policy Board is being formed by the Association, to provide the overall guidance to CSA activities in this field.

The scope of the program is potentially very wide because it appears to offer benefits to all sectors of the manufacturing and processing industries as well as to many service organizations. It is planned that the program be introduced one industry or sector or group at a time, as staff capability is expanded. It is considered preferable for smaller segments of industry to be activated and the initial work completed relatively quickly, rather than to offer a wide-ranging program initially which cannot then be serviced on a timely basis.

The rate of progress will be partly dependent on the availability of assessment teams, but will depend more on the amount of activity a company applies to having their program operating completely and effectively. The team has the responsibility of assessing that which is happening; the company has the responsibility of making it happen.

Having a single organization responsible for the management of assessment and audits offers further benefits to the program because any problem areas will be treated equitably and the interpretations given will be uniform. A program of this nature must not only be equitable but must be seen to be equitable.

Program Acceptance

A coordinated program, such as outlined above, can only be considered fully successful and provide maximum benefits when it is accepted by effectively all those purchasers, users and authorities who would otherwise need to perform the work themselves. To this end, we are working to get the program known and understood.

We have had some discussions, and more are planned, with large purchasers - who are also the final owners in many cases - and with Authorities so that they are aware of what the program can offer and also to acquaint them with what the program will not do for them. There will be further discussions with various trade groups and associations to ensure that there is adequate two-way communication with those who are actively involved, and these are expected to take place as we are able to offer the program in their product areas.

As noted earlier, the technical side of the program must be complete and effective, because otherwise the whole activity becomes superficial and offers false security at best. Executed properly, it offers the advantages of a coordinated, standardized approach to the uniform qualification of QA systems, without duplication of effort.

Conclusion

Because the introduction of a quality assurance program into a supplier's operation seems to consistently pay dividends, there are direct benefits to the supplier. When a purchaser buys from a supplier who successfully operates a quality assurance program he has a greater assurance that he will receive what he needs and will also typically receive it on the agreed schedule. Similarly, the Authority having Jurisdiction can have a greater confidence that both the spirit as well as the letter of the law is being met.

This program is not intended to reinvent the wheel, nor to duplicate what is already being carried out by others but to coordinate the various efforts now being expended. It follows naturally from our corporate objective - Services in Support of Standardization.

This is a most exciting time for those of use who are involved with QA because we are on the threshold of a program which can offer significant benefits to all - supplier, purchaser, company and country.

EXTENDING EFFECTIVENESS OF QUALITY COST PROGRAMS

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EVOLUTION OF QUALITY COST PROGRAMS

Does your company have a quality cost program? If so, would it be classified as active or passive? What primary purpose did the program originally serve? What purpose does it serve now? And, most importantly, what reaction does it generate within your executive offices?

The answers to questions like these would prove very interesting, if it were possible to obtain factual replies from all American business concerns with more than 500 employees. While no valid studies are available, the A.S.Q.C. Quality Cost Technical Committee has reason to believe the following relationships would probably apply:

1. The majority of companies still do not use any formalized quality cost program.
 - o Most manufacturing companies regularly monitor certain key quality cost elements, such as scrap, rework, inspection budget costs, etc.
 - o Other management techniques are frequently employed, which may bring considerable temporary cost consciousness to particular products or departments. Examples include:
 - A. Budget controls and restrictions.
 - B. Value Engineering or cost reduction studies.
 - C. Cost improvement goals within Management By Objectives.
 - D. Employee suggestion systems.
 - E. Management bonuses, incentive systems, and profit sharing.
 - o Formal quality cost programs are quite rare within Service Industries, or companies having high service-to-product ratios.
2. Use of formalized quality cost programs is steadily growing within Manufacturing Industries, and there is a noticeable quickening in growth rate.
 - o In 1967, when the first edition of "Quality Costs - What & How" was published, quality cost analysis was mainly an unknown academic curiosity within technical circles of the quality profession.
 - o In 1971, when the expanded second edition of this manual was published, these techniques had been accepted in principle by only the most progressive of Manufacturing Industries, and experimental programs had begun.
 - o By 1977, when "Guide For Reducing Quality Costs" was published, routine use of quality cost analysis was an accepted practice for a significant minority of manufacturing companies. Still others were just instituting trial programs.
 - o Within the past five years, interest levels have been progressively increasing, as indicated by attendance at the tutorial and management sessions at the Annual Technical Conferences, regional, divisional and section symposiums.

3. Initial applications of formal quality cost programs are usually directed towards specific pre-existing malignancies of major proportions.
 - o Quality cost techniques are used to identify and focus attention on these known aggravated problems, (generally product lines or manufacturing processes).
 - o After quantification, priority managerial approval is obtained to mount a coordinated attack by all concerned parties.
 - o Cost analysis reports document the early economic results of this campaign, until all proposed corrective actions have been implemented, (or other crises require reduction in attack effort).
 - o Subsequent reports document the longer term impact of the earlier task team corrective actions, and soon reports become very routine until a new crisis causes the cycle to be repeated.
4. The normal use of a quality cost program may, therefore, deteriorate into a "scorecard" posting, with little sustaining executive influence.
 - o Reports serve chiefly as a reminder of previous "glorious accomplishments", plus a general reassurance that present day quality is still "in control".
 - o Complacency is further promoted through favorable comparison with:
 - A. Non-exact general industry approximations.
 - B. Past company history before any quality cost program.
 - C. Conservative or "safe" company goals.
 - o Most quality cost programs are maintained only on a composite company or divisional basis, without ready segregation of specific product lines or manufacturing processes.
 - o Unless violent unfavorable events occur, little effect may be indicated in the overall "scorecard" rating.
 - o When used only in a passive manner, the analysis indicates results which have already occurred, with no opportunity to change what is now past history. This further increases the "scorecard syndrome" on the part of executive reaction!

QUALITY COST ANALYSIS - SO WHAT?

Unless dynamic response is introduced into your quality cost program, it may be found that your company's reaction will have rotated full circle from "Quality Cost Analysis - What's That?" to "Quality Cost Analysis - SO WHAT?" Companies should not use a quality cost program simply for the sake of using one, or because they believe they have a better quality cost rating than the average company in their line. And they certainly shouldn't start one because best Q.A. theory indicates it is the right way to do things. It is much more important to "do the right things" than it is to "do things right"!

DOING THE RIGHT THINGS

From an executive management viewpoint, what type of "right things" need to be done in which Quality Assurance can exert a positive influence? Examples include:

- o Early identification of problems, with assessment of magnitude and trend patterns.
- o Establishment of priorities for efficient utilization of available limited resources, and decision making.
- o Administrative structuring to have middle management exercise active responsibility, within their authority, for total company

interests.

- o Combat complacency and inertia through actions to improve the status quo.

A well designed quality cost program can be an effective management control tool, instead of simply a "scorecard" of composite quality cost attainment. But, how can this happy state be achieved?

An active quality cost program will assist and permit the manage-
ment of total quality costs consistent with company policy. But, to
"manage", we must control. To "control", we must measure. To "measure",
we must define. In "defining", we must quantify. Keeping these ele-
mentary requirements in mind, the following guidelines are presented for
construction of a powerful quality cost program.

ANATOMY OF A DYNAMIC QUALITY COST PROGRAM

1. Provide for detailed cost identification and segregation down to the lowest level where control is desired.

Remember, in combined form, the individual elements are not capable of measurement, and therefore can't be controlled. It may not be necessary to segregate each individual product model, but general product lines or families should be separated from other costs. Within manufacturing facilities, consider whether "machine shop" might be too broad a listing, and yet "machine lathes", "turret lathes", "multi-spindle", and "automatic screw machines" might all be combined into "lathe family".

2. Reflect all identified factory or field quality costs back to the vertical lines responsible for the products and services involved. This includes allocating the entire Quality Department budget!

Don't lump any quality cost elements into big, nondescript collections, such as "field service costs", or "general scrap". Should the Field Service Manager be held accountable for the costs associated with servicing field products which become defective during the warranty period, or should the responsible Vertical Line Manager? Should not that responsibility include all factory and field costs identified with that product or service? If so, then the Q.A. and Inspection costs attributed to the support of that product (both in the factory and in the field) should also be allocated back to that Vertical Product Line. Generally speaking, all identified or allocated costs should reflect back to the same organizational groups which received credit for the units of production, and net sales billed.

3. Establish bold cost improvement objective goals, which are believed to be achievable, but only through sustained, hard effort.

Don't establish next year's goals based upon actual costs for this year, plus an allowance for inflation. This keeps increasing management's "threshold of pain" to the point of insensitivity to all but major calamities. Long established costs do not necessarily mean unavoidable costs. Challenge them!

4. The cost improvement objectives established should be incorporated as personal goals of the lowest managers who have overall discretionary authority for the product or service involved.

Individual objectives for the product lines or services should then be combined as composite objectives upwards within the chain of command, in the same manner as line responsibilities are combined upwards. How else can you require these managers to control their quality costs in the same manner they now control their direct and indirect costs, and manage their production schedules?

5. Consider all high quality cost elements as being potential cost breakthrough opportunities.

Use Pareto analysis and trend analysis techniques to identify such opportunities for concentrated attack through design, material, process, methods and equipment challenges. Initiate Value Engineering studies, and invite suggestions from the people who work on the product line or in the processing area involved. Compare how your competitors handle that aspect within their products. Consider new technology which has been introduced since your design or process method was first implemented.

6. Incorporate specific quality cost objectives into all new or improved product design efforts, or services offered.

Quality cost objectives should be just as important as formal estimates of direct production costs, which are normally a specified criteria of every new release. (Also, don't forget that MTBF goals should be included in all Sales-Engineering project specifications for new releases.) In the same manner as the direct cost estimates, quality cost objectives should be agreed to by the Vertical Line Manager who will finally be responsible for the new release. Until achieved or renegotiated, Engineering should be held jointly responsible with the Vertical Line Manager for excessive direct or quality costs associated with the new product release.

7. Require rapid collection of current data, and perform timely trend analysis using appropriate multiple bases.

The object of this exercise is the creation of an "early warning system", to permit necessary interim, adaptive and corrective actions. Rapid actions will prevent or limit additional avoidable losses from being sustained. Doing this will provide the dynamic response needed to overcome the historical "scorecard syndrome".

8. Use the quality cost program to manage the available Quality Assurance budget and resources where they will be most effective.

Whether your departmental budget and resources are generous or meager, stop doing other people's work for them, and concentrate on your own major quality responsibilities. As Quality Manager, you are not responsible to cure every problem discovered! But you are responsible to see that each such problem is properly addressed by the appropriate action parties, and then satisfactorily resolved!

BENEFITS OF A DYNAMIC QUALITY COST PROGRAM

Quality Assurance should intensify efforts towards the identification of existing or potential problems, assessing their magnitude and impact, referral to the proper parties for resolution, and monitoring corrective action efforts and effectiveness of same. In all these endeavors, a dynamic quality cost program could be the vehicle to manage the majority of these efforts.

Such a quality cost program would then be truly an effective management control tool, and not just a historical "scorecard" grade. Just as a machine tool provides a distinctive mechanical advantage, so this diagnostic control tool provides a distinctive "managerial advantage". This advantage can then be directed towards more effective management decisions, increased profitability, better return on investment, improved utilization of Quality Department resources, and elimination or improvement of product lines or services with marginal future economic worth. Isn't this a giant-sized improvement over former intuitive or stereotyped management methods? It can assure a progressive company of increased profitability and cost effectiveness, and permit it to engage in keener competition with smaller risks. That, in turn, can mean greater market share, whether times are good or bad.

THE QUALITY ASSURANCE CHALLENGE

Have you offered the executive management of your company a dynamic quality cost program yet? Consider how your competitive position might now have been improved, if such a program had been implemented two years ago! Can you afford to wait until after your major competitor has one in operation?

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LCS 300:10:000

"A METHOD FOR PREDICTING WARRANTY COSTS"

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Data generated in a reliability evaluation of a product can be an important starting point for predicting potential costs involved with product failure at any future point in time. A conversion of failure rates into cost data can prove to be a valuable information contribution to business managers in forming decisions about continuation of a product program or at least provision of initial and ongoing capital budgeting plans for a potential product's production and introduction to its market.

The objective of this paper is to illustrate a method for translating a product's reliability profile and design alternative considerations into a cost structure that can provide business management with information they can understand. The extra steps of this method could prove worthwhile in simplifying illustration of the underlying potential warranty problems and associated costs that might not be truly understandable in its original technical form.

Basically, the three parts of the method are the original reliability evaluation of a design and its alternatives, the application of Markov Chain Theory in extending failure rate data into the future, and the analysis of applied costs to this point by the net present value method in order to determine project profitability potentials between the original design and its alternatives. Markov Chain construction can provide information about summation of product failures at future points in time as production continues and the population of product in use increases. This profile provides information about product in use accumulation distribution that is necessary for providing a base to which design failure rate information can be applied in predicting the probable quantities rate of return of failed goods. Of course, return of goods may be covered under both implied product warranty as well as stated warranty policy.

In order to explain the method, an actual example has been selected to illustrate the steps taken in arriving at project cost information that will be in a simplified form that business managers can find to be usable in forming decisions about a project's viability and continuation. Although this project example is real, certain elements have been changed so as to prevent recognition of the actual product. This author believes that the changes that have been made to prevent recognition of the product do not materially affect the outcomes contained in the example's illustrations. The example selected is a small analog computer that has a fixed program for controlling a mechanical function of some machinery. Knowing the actual controlling outputs of this device are not necessary to understanding the evaluation of the reliability of the product. However, let us end this product's application with the note that it is an integral part of a higher order system. The product part we will use in our illustration is not maintainable, but is replacable in the overall system.

The computer is composed of a variety of electronic components mounted on three stacked PC boards. These electronic components consist of the usual varieties including transistors, pots, capacitors, integrated circuits, diodes, resistors, etc. Our study will be confined to the transistors, ICs and diodes involved in the design. The original design contains the following quantities of each component under study: IC's - 2, Transistors - 14, Silicon Diodes - 25.

Reliability information about these components is drawn from MIL-HDBK-217B, "Reliability Prediction of Electronic Equipment". Table 1. contains a summary of this information as used in this study. Data was generated for components operating at 25° C ambient and at two levels of quality, ie: commercial vs military, (Jan). Table 1. contains the pertinent information concerning the design alternatives under consideration. This information includes the combinations of commercial versus military quality components for each design alternative which in turn influence the total unit failure rate. Of course, the total unit incorporates other components which for simplicity in this example are considered held constant. Additional information contained in Table 1, is the cost to build per unit which takes into account the added cost of "burn in" and sort testing of military quality components. Comparing the failure rate column with cost to build does not clearly define a relationship as to which combination delivers the optimal reliability to cost relation. Thus the business decision becomes quite difficult

unless additional means of analysis is found to overcome the indecisiveness of this problem. The method we will propose is one means of bridging the current state of our problem.

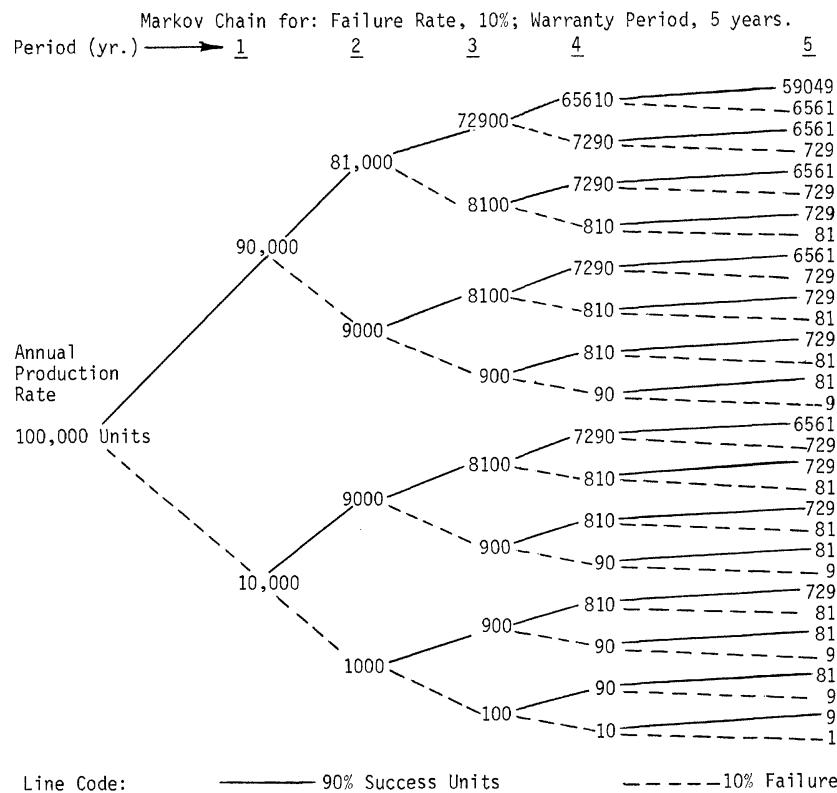
TABLE 1

Design Alternative	Component Quality Levels			Failure Rate %	Cost to Build/unit
	IC	Diode	Transistor		
1	c	c	c	12.6	\$30.00
2	m	c	c	5.9	30.14
3	m	m	c	3.8	31.89
4	m	c	m	4.6	31.54
5	c	m	c	10.5	31.75
6	c	m	m	9.3	33.15
7	c	c	m	11.2	31.40
8	m	m	m	2.5	33.29

m - military, (Jan) c - commercial

Let us assume that we must generate a returned goods rate based on the failure rates indicated in Table 1, for each component design quality level. The method used is the Markov chain. Application of this technique will develop the number of units expected to fail within each time segment of the warranty period. Our example will utilize a five year warranty period. Instead of developing Markov chains for each of our eight design alternatives, we shall only develop an example of a Markov chain for a 10% failure rate over a 5 year warranty period. Figure 1 is the graphical illustration of this example Markov chain.

FIGURE 1



Note that failures are replaced with additional production in the following time segment

and that those replacement units are subject to the same failure rate in each time segment. The Markov chain is an excellent tool to handle this condition for production replacement. Table 2 is a summation of the Markov chains for each design alternative in the example.

TABLE 2

Design Alternative	Sale Type	Warranty Year				
		1	2	3	4	5
1.	Original	100,000	111,012	122,024	133,036	144,048
	Replacement	12,600	14,188	15,776	17,364	18,952
	Total Prod.	112,600	125,200	137,800	150,400	163,000
2.	Original	100,000	105,552	111,104	116,656	122,208
	Replacement	5,900	6,248	6,546	6,944	7,292
	Total Prod.	105,900	111,800	117,650	123,600	129,500
3.	Original	100,000	103,656	107,311	110,967	114,622
	Replacement	3,800	3,944	4,089	4,233	4,378
	Total Prod.	103,800	107,600	111,400	115,200	119,000
4.	Original	100,000	104,388	108,777	113,165	117,554
	Replacement	4,600	4,812	5,023	5,235	5,446
	Total Prod.	104,600	109,200	113,800	118,400	123,000
5.	Original	100,000	109,398	118,795	128,193	137,590
	Replacement	10,500	11,603	12,705	13,808	14,710
	Total Prod.	110,500	121,001	131,500	142,001	152,500
6.	Original	100,000	108,435	116,870	125,305	133,740
	Replacement	9,300	10,165	11,030	11,895	12,760
	Total Prod.	109,300	118,600	127,900	137,200	146,500
7.	Original	100,000	109,946	119,891	129,837	139,782
	Replacement	11,200	12,454	13,709	14,963	16,218
	Total Prod.	111,200	122,400	133,600	144,800	156,000
8.	Original	100,000	102,437	104,875	107,313	109,750
	Replacement	2,500	2,563	2,625	2,688	2,750
	Total Prod.	102,500	105,000	107,500	110,001	112,500

Combining information from tables 1 and 2 and figure 1 allows development of information for tables 3 and 4. (Note: Due to the size of tables 3 and 4, they are contained in Appendix B). Table 3 is the business information matrix leading to the NPV of table 4. A discussion of each element in Table 3 will allow an understanding of each idea. The design alternative is taken from Table 1 and indicates the mix of commercial quality to military quality in the three components. The year column signifies each year in the warranty period. Units for sale is taken from Original Sale Type in Table 2. Cash In Flow at \$50 is the total income of units for sale at a price of \$50 per unit. Units Built is the sum of original production and replacement production based on Markov chain outcomes at each design alternative failure rate. Cost to Build is the product of Units Built times the cost of manufacture. Again, unit cost of manufacture is based on the mix of military to commercial quality of the three basic electronic components we are studying in our example. Units Returned Warranty is the sum per period of failures calculated in the Markov chain. Additional Cost @ \$25 Warranty is the product of Units Returned times the cost of handling warranty that is additional to the production cost shown in the Cost to Build column. Cash Outflow is the difference between the column, Cash Inflow @ \$50, and the summation of the columns, Cost to Build plus Additional Costs @ \$25 Warranty.

Table 4 represents the steps in calculating the net present value for each of the design alternatives. This is the business decision matrix. The first column is Cash Outflow. This column is the ending column in Table 3. The next column is Depreciation of capital assets. For simplicity, we have selected the straight line depreciation method for a five year period. Net Income B_4 Taxes is the difference between Cash Inflow and the summation of Cash Outflow plus Depreciation. The next column, Net Income After Taxes is based on a corporate tax rate of 48%. (Note: The corporate tax rate may vary according to changes in tax law and may be subject to change. This means that the reader should check the current corporate tax rate before using the method.) Net Cash Flow shows the first figure as a negative number. This figure is the cost of capital for the project term, in our case 5 years. The negative figure is also the sum of the Depreciation column for the project term. The remaining figures in Net Cash Flow are the difference between Net Income B_4 Taxes and Net Income After Taxes. The second from the last column is the rate of discount. This is the rate available to borrowers of capital on the money market at the time the project is being considered. The final column, NPV is the product of the Net Cash Flow times the value of the discount rate in that year of the project. Discount rate values are usually obtainable from discount

tables contained in many texts in Accounting, Finance, Managerial Economics, etc. The project with the highest project NPV is the most desirable business alternative provided assumptions we have made hold true for the project term. Limiting assumptions are; cost of capital is correctly defined; corporate tax rates do not change; discount rates will hold fairly steady; etc.

TABLE 5					
Design Alt.	Failure Rate (%)	Production Cost Per Unit	5 Yr. Total Net Income After Taxes	5 Yr. Total Sales	5 Yr. Period Net Present Value
1	12.6	\$30.00	\$4,004,000	\$30,506,000	\$3,044,128
2	5.9	30.14	4,688,770	27,776,000	3,596,890
3	3.8	31.89	4,344,064	26,827,810	3,338,260
4	4.6	31.54	4,378,421	27,194,200	3,361,391
5	10.5	31.75	3,658,014	29,698,800	2,783,744
6	9.3	33.15	3,348,448	29,217,500	2,547,167
7	11.2	31.40	3,683,680	29,972,800	2,802,026
8	2.5	33.29	4,054,540	26,218,750	3,118,676

Table 5 summarizes pertinent information from the myriad of calculations in previous tables. The first three columns have already been explained, but are included to define individual project identities. Column, 5 Yr. Total Net Income is the sum of the project term figures from the Net Income column in Table 4. 5 Yr. Total Sales is the sum of the Cash Inflow column in Table 3, and 5 Yr. Period Net Present Value is Total NPV in Table 4.

Analysing the results indicates that from a business decision viewpoint, design alternative 2 is the most feasible, relating to NPV. It is also most feasible when considering Net Income After Taxes. However, it is not the most powerful when solely considering total sales. It isn't too bad when evaluating unit production cost.

From the Engineering viewpoint, design alternative 8 would be most feasible since it indicates the lowest failure rate. If the product in fact does require high reliability considerations in use, note that the NPV is fourth best. The balance between technological and business evaluation is fairly good. The value of this method gives information that can allow a less uncertain environment in which a decision can be made.

The method outlined attempts to apply business decision techniques to technological evaluation in order to create a less risky environment in which project selection must be conducted. Cost information applied to technological reasoning rounds out the manager's decision making responsibility toward a higher level of certainty. If the limiting assumptions do in fact hold true for the period under study, we find that this method can actually allow for control of the amount of warranty returns and associated costs in each period by selecting the design alternative most appropriate to the business and technical environment conditions and criteria.

APPENDIX A

Bibliography

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APPENDIX B

Table 3

Des. Alt.	Yr.	Units For Sale	Cash In Flow At \$50	Units Built	Cost To Build	Warranty Units Returned	Warranty Costs at \$25/Unit	Cash Out Flow
<u>@ \$30.00</u>								
1	1	100000	\$5000000	112600	\$3378000	12600	\$315000	\$3693000
	2	111012	5550600	125200	3756000	14188	354700	4110700
	3	122024	6101200	137800	4134000	15776	394400	4528400
	4	133036	6651800	150400	4512000	17364	434100	4946100
	5	144048	7202400	163000	4890000	18952	473800	5363800
<u>@ \$30.14</u>								
2	1	100000	5000000	105900	3191826	5900	147500	3339326
	2	105552	5277600	111800	3369652	6248	156200	3525852
	3	111104	5555200	117650	3545971	6546	163650	3709621
	4	116656	5832800	123600	3725304	6944	173600	3898904
	5	122208	6110400	129500	3903130	7292	182300	4085430
<u>@ \$31.89</u>								
3	1	100000	5000000	103800	3310182	3800	95000	3405182
	2	103656	5182800	107600	3431364	3944	98600	3529964
	3	107311	5365550	111400	3552546	4089	102225	3654771
	4	110967	5548350	115200	3673728	4233	105825	3779553
	5	114622	5731110	119000	3794910	4378	109450	3904360
<u>@ \$31.54</u>								
4	1	100000	5000000	104600	3299084	4600	115000	3414084
	2	104388	5219400	109200	3444168	4812	120300	3564468
	3	108777	5438850	113800	3589252	5023	125575	3714827
	4	113165	5658250	118400	3734336	5235	130875	3865211
	5	117554	5877700	123000	3879420	5446	136150	4015570
<u>@ \$31.75</u>								
5	1	100000	5000000	110500	3508375	10500	262500	3770875
	2	109398	5469900	121001	3841782	11603	290075	4131856
	3	118795	5939750	131500	4175125	12705	317625	4492750
	4	128193	6409650	142001	4508849	13808	345200	4854049
	5	137590	6879500	152500	4841875	14910	372750	5214625
<u>@ \$33.15</u>								
6	1	100000	5000000	109300	3623295	9300	232500	3855795
	2	108435	5421750	118600	3931590	10165	254125	4185715
	3	116870	5843500	127900	4239885	11030	275750	4515635
	4	125305	6265250	137200	4548180	11895	297375	4845555
	5	133740	6687000	146500	4856475	12760	319000	5175475
<u>@ \$31.40</u>								
7	1	100000	5000000	111200	3491680	11200	280000	3771680
	2	109946	5497300	122400	3843360	12454	311350	4154710
	3	119891	5994550	133600	4195040	13709	342725	4537765
	4	129837	6491850	144800	4546720	14963	374075	4920795
	5	139782	6989100	156000	4898400	16218	405450	5303850
<u>@ \$33.29</u>								
8	1	100000	5000000	102500	3412225	2500	62500	3474725
	2	102437	5121850	105000	3495450	2563	64075	3559525
	3	104875	5243750	107500	3578675	2625	65625	3644300
	4	107313	5365650	110001	3661933	2688	67200	3729133
	5	109750	5487500	112500	3745125	2750	68750	3813875

APPENDIX B

Table 4

Des. Alt.	Yr.	Cash Out Flow	Straight Line Dep.	Net Income Before Tax	Net Income After Tax @ 48%	Net Cash Flow	Discount @ 8.75%	NPV
1	0					-\$200000	1.0000	-\$200000
	1	\$3693000	\$40000	\$1267000	\$658840	698840	.9195	642583
	2	4110700	40000	1399900	727948	767948	.8456	649377
	3	4528400	40000	1532800	797056	837056	.7775	650811
	4	4946100	40000	1665700	866164	906164	.7150	647907
	5	5363800	40000	1834600	953992	993992	.6574	653450
						Total NPV =		3,044,128
2	0					-\$200000	1.0000	-\$200000
	1	3339326	40000	1620674	842750	882750	.9195	811689
	2	3525852	40000	1711748	890109	930109	.8456	786500
	3	3709621	40000	1805579	938901	978901	.7775	761096
	4	3898904	40000	1893896	984826	1024826	.7150	732751
	5	4085430	40000	1984970	1032184	1072184	.6574	704854
						Total NPV =		3,596,890
3	0					-\$200000	1.0000	-\$200000
	1	3405182	40000	1554818	808505	848505	.9195	780201
	2	3529964	40000	1612836	838675	878675	.8456	743007
	3	3654771	40000	1670779	868805	908805	.7775	706596
	4	3779553	40000	1728797	898974	938974	.7150	671367
	5	3904360	40000	1786740	929105	969105	.6574	637089
						Total NPV =		3,338,260
4	0					-\$200000	1.0000	-\$200000
	1	3414084	40000	1545916	803876	843876	.9195	775944
	2	3564468	40000	1614932	839765	879764	.8456	743929
	3	3714827	40000	1684023	875692	915692	.7775	711950
	4	3865211	40000	1753039	911580	951580	.7150	680380
	5	4015570	40000	1822130	947508	987508	.6574	649187
						Total NPV =		3,361,391
5	0					-\$200000	1.0000	-\$200000
	1	3770875	40000	1189125	618345	658345	.9195	605348
	2	4131856	40000	1298043	674982	714982	.8456	604589
	3	4492750	40000	1407000	731640	771640	.7775	599950
	4	4854049	40000	1515601	788112	828112	.7150	592100
	5	5214625	40000	1624875	844935	884935	.6574	581756
						Total NPV =		2,783,744
6	0					-\$200000	1.0000	-\$200000
	1	3855795	40000	1104205	574187	614187	.9195	564745
	2	4185715	40000	1196035	621938	661938	.8456	559735
	3	4515635	40000	1287865	669690	709690	.7775	551784
	4	4845555	40000	1379695	717441	757441	.7150	541571
	5	5175475	40000	1471525	765193	805193	.6574	529334
						Total NPV =		2,547,169
7	0					-\$200000	1.0000	-\$200000
	1	3771680	40000	1188320	617926	657926	.9195	604963
	2	4154710	40000	1302590	677347	717347	.8456	606588
	3	4537765	40000	1416785	736728	776728	.7775	603906
	4	4920795	40000	1531055	796149	836149	.7150	597846
	5	5303850	40000	1645250	855530	895530	.6574	588721
						Total NPV =		2,802,026
8	0					-\$200000	1.0000	-\$200000
	1	3474725	40000	1485275	772343	812343	.9195	746949
	2	3559525	40000	1522325	791609	831609	.8456	703209
	3	3644300	40000	1559450	810914	850914	.7775	661586
	4	3729133	40000	1596516	830189	870189	.7150	622185
	5	3813875	40000	1633625	849485	889485	.6574	584747
						Total NPV =		3,118,676

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PROBLEM SOLVING COMPARISONS: QC CIRCLES, KT, ETC.

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INTRODUCTION

During the past twenty years, there have grown up a number of procedures to identify and solve problems. The ones this paper specifically examines are Kepner-Tregoe Analysis (KT), Quality Control Circles (QCC), and Zero Defects (ZD). This is not to say that there are not other systems. We have chosen these three chiefly because they are fairly well known and some of you may work in firms which presently use them. The paper looks at these techniques in light of how each one works to solve problems. That is, how does each define the term problem; what kinds of problems does each attack; who solves problems; what procedures and tools does each technique use; what type of training, if any, do the problem-solvers receive; and what is the creativity-quotient of each method. It will be helpful, before we go on into the body of the paper, if first we define 'problem' and 'problem-solving'. Then it will be easier to see how well the different techniques fit the definitions. We can view the term 'problem' in the following ways. A problem is a discrepancy or difference between an actual state of affairs and a desired or ideal state of af-

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fairs. Another way of saying it is, that a problem is a "gap between current results (or ends) and desired results (or ends)". A problem exists whenever there is an imbalance between what should be and what actually is; or whenever there is a deviation from a standard. The key words in these definitions are 'deviation', 'gap', 'imbalance', 'discrepancy', 'difference'. Quite simply, problem-solving is the means we use to reduce the gap, imbalance, or difference between what is and should be. It is how we get to where we want to go from where we are.

DEFINITION OF PROBLEM

KT: The definition of 'problem' contains two corollary ideas. The first says that a problem is a deviation from a standard. On the other side is the idea of problem being the imbalance between what actually happens and what should happen.

QCC: The concept of problem contains the idea of deviation from a standard as well as that of gap between the actual and ideal. This view of what constitutes a problem appears to be the same as in KT, but there is a subtle difference in the two which shows up in the kinds of problems each procedure addresses.

ZD: Problem is seen in a specific, all-be-it limited, way, i.e. as deviation from a set standard, perfection, and such deviation results in errors or defects. In other words, if every employee did his/her job right there would be no errors, no defects.

KINDS OF PROBLEMS ATTACKED

KT: The type of problem KT addresses is by and large the sporadic one. This is evident in the KT definition of problem since this definition includes the concept that the deviation or imbalance is always caused by an unexpected, unplanned change. This view implies that something has occurred at a specific point in time.

Up until the change, the process is acceptable. KT procedure is an example of end-product-well-defined because its aim is to stop the sporadic happening and to return to the predetermined standard. KT works well in the area of management-controllable problems such as in the example of the blackened filaments, chapter two of the Rational Manager.

QCQ: The basic thrust of activity aims at the solution of relatively low level problems which are chronic in nature. That is the discrepancy between actual and ideal or the deviation from standard has been happening over a period of time and may or may not have been occasioned by a marked change. The process may be operating up to standard but may not be at ideal performance. Moreover the process itself may cause the discrepancies between actual and desired and/or deviations from standard. These conceptions differ from the KT approach in-as-much as KT addresses a different sort of problem.

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Generally the problems handled by the Circles are operator-controllable. The operator knows what he/she is to do and what he/she actually is doing and has the means to regulate the job. Consequently the Circle members themselves find, analyze and implement solutions to work-problems such as defects or scrap reduction. QC Circle activity looks to the long-run performance. It solves the problem and initiates follow-up, guidelines and safeguards for the solutions.

(10)

ZD: This program works to reduce defects by prevention. ZD theory says that defects are operator-controllable. Since the operator already has all he/she needs to do the job, knowledge and tools, there will be no errors, i.e. defects, if only the employee cares enough to work accurately according to pre-established standards.

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However, there are certain kinds of problems workers under a ZD program cannot address. These are ones which arise from difficulties in the process itself. These types of problems are routinely handled by QC Circle whereas, in the ZD program, they are handled by supervisors, ZD administrators, or production or quality engineers.

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WHO SOLVES PROBLEMS

KT: Essentially it is the manager who is the problem-solver. He is responsible for analyzing the problem, making the decision to put to work whichever solution he has selected, and preparing preventive action.

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From others who are involved with the area under study, the manager elicits help and information in analyzing and solving the problem.

(15)

QCQ: Problem solving in the Circle is primarily a team effort. The Circle is a small group of people who work in the same area, together with their foreman/supervisor. They usually choose the particular problem themselves, then analyze it, find and implement solutions. Participation by each member of the Circle is essential and everyone's responsibility. The Circle functions as a team and "stars" are not encouraged. There may be interaction with Circles in other work areas if the problem is that broad. For example, a Circle in the warehouse might work with a Circle in final assembly to prevent cracking of glass tanks. Personnel from quality assurance, engineering, or other areas serve as resource people.

ZD: This is a broadly based program which applies to all levels of the organization. In one sense each person in the organization is a problem solver because he strives to improve his own performance, to work without error. However, in the sense that problem solving is used in this paper, the responsibility for solving

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problems rests with the supervisor and/or ZD Administrator and a team which is not directly involved with the work area. The supervisor corrects problems discovered by the workers and reported on the Error Cause Identification (ECI) form. Should the problem prove too difficult or require handling by superiors, the supervisor passes to the ZD Administrator or other appropriate officials. The man on the line has no responsibility to solve problems other than to remove defects. Should he spot a problem in the process, he is encouraged to fill out an ECI form and for-

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ward it to his supervisor. If he has thought of a solution, he submits this through
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the suggestion system.

PROBLEM SOLVING SEQUENCE

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"Problem solving is a process that follows a logical sequence." The process by whatever name contains familiar and recognizable steps: once the problem is recognized, the problem-solver looks for causes. He collects information about it from what he observes. Next he speculates about the causes, analyzes them, develops
(20)
solutions, chooses one and puts it to work, always revising as necessary.

KT: Messrs. Kepner and Tregoe have developed a very orderly and precise method for analysis of problems, for making decisions and obviating potential difficulties in the solution. We give here a brief summary of this procedure, based on material
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from Results Planning Manual, the KT workbook. The procedure has three parts, Problem Analysis, Decision Analysis, and Analysis of Potential Problems. Problem Analysis is the systematic way of finding the real cause of the problem. First specify exactly what the problem is and is not, noting areas of sharp contrast. Next develop possible causes. Test each possibility to determine the probable cause. Verify the results.

Decision Analysis is the method used to choose the best solution to the problem. First, establish the objectives, what are the desired results and what are the necessary resources. After the objectives are clear, classify as must: the critical area; and want: those things of relative importance. Next, find alternatives. Compare these to the objectives for consequences.

Potential Problem Analysis anticipates potential problems and devises plans to prevent their occurrence or to protect the solution from the impact of the potential problem if it should occur.

QCQ: The first step in the problem solving sequence followed by the Circles is
(22)

to identify goals. Usually the goals are fairly broad, such as reduction of scrap or defects in a particular department. In order to narrow the goal to a workable size, the Circle breaks down the general problem area into its components. At this stage the Circle collects data by means of check sheets, tallies, etc. The Circle proceeds to analyze the data by means of Pareto analysis which sets priorities and by frequency histograms. In determining causes, the Circle employs brainstorming, and records ideas on a Cause and Effect diagram (C & E). Incidentally, it is well to note Kepner's and Tregoe's caution about brainstorming that the technique "does not lead to an understanding of precisely what is wrong, how things got that way, and
(23)

what is the most economical way of correcting the trouble." When the Circles brainstorm, they are looking at four precise areas where trouble can arise: men, method, material or machine. By using the C & E Diagram, the Circle members can graphically see the interrelationships of different aspects of the problem under analysis.

The next step is to experiment to see which ideas recorded on the C & E Diagram are the most likely causes. The circle analyzes these results using graphs and other statistical analysis. Once a solution is selected, the Circle tests and implements it. The Circle also designs and implements safeguards to make sure the solution continues to function properly.

In some respects this problem-solving sequence resembles the KT approach. The Circles specify the problem through statistical tools such as Pareto analysis, frequency histograms or check sheets. It is in the brainstorming phase that the Circles develop possible causes. Both KT and the Circles test for the probable cause and verify the results.

The KT procedure seems to follow a more definite pattern in order to determine what the solution is than do the QC Circles. The Circles have selected a goal beforehand, such as reducing per cent defective parts, before analyzing the causes. Both procedures choose solutions. The Circles test the solutions to find potential problems. By designing and implementing safeguards, the Circles, just as KT analysis, provide for protection and contingent action.

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The dissimilarities in the two approaches appear because the methods deal with different orders of problem. The QC Circle solves low level, chronic problems; KT handles sporadic serious problems.

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ZD: The ZD program seeks to motivate or encourage people to do their job right the first time, every time. Generally speaking ZD aims toward the solution of a single specific problem: reduction of defects by prevention rather than through detection. The program was not designed to solve problems nor was it intended to teach techniques for solving problems.

(26) (27)

Even so a type of problem solving procedure does take place in Error Cause Identification. The employee recognizes that a problem exists which either does, or has the potential to, cause errors. He fills out an ECI form which he submits to his supervisor. The main responsibility for solving the problem rests with the supervisor.

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Then the supervisor verifies that a problem exists, determines what must be done to correct it, and then puts into operation whatever solution he has chosen. In some instances the quality control representative and possibly an assigned team find the solution.

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We would like to take a look at an instance of problem solving in the example given by J. M. Halpin in Zero Defects. The supervisor discovered an increase of surface scratches on a product. The cause is supposed to result from careless and/or improper handling. The supervisor speaks to his workers about the scratches. When the scratches continue to occur, the supervisor calls in the ZD Administrator. This person checks the end result of scratches on the finished product. He finds that this defect can cause the ruin of the finished product. The Administrator demonstrates to the workers what he has found.

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The manner in which the supervisor handled this particular case, as it is reported, points to a type of difficulty noted by Dr. Ishikawa, and Dr. Juran. The supervisor assumes that the cause of the scratches is careless handling, but it might well have come from defective tools or the process itself. No one verified the cause using standard statistical methods.

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TRAINING IN PROBLEM SOLVING

KT: The manager receives training in KT analysis through study of the principles as outlined in The Rational Manager and through participation in a KT training session. An essential part of this training is the practice of the concepts in simulated and personal business situations. These practice sessions are critiqued by the KT instructor.

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QC: The supervisor receives extensive training in group dynamics and basic statistical tools: histograms, Pareto analysis, control charts, stratification, binomial probability paper, cause and effect diagrams, graphs, etc. He, in turn, trains the people who work under him in these same techniques. Training is not limited to job training, honing of work skills or improving understanding of the process. Workers may indeed receive this sort of training if the Circle finds that more job training is part of the solution to the problem it has tackled.

The skills that the worker in a QC Circle learns are practical statistical concepts. In KT the manager learns an efficient method for breaking down a problem and deciding how to solve it. He would further enhance his problem solving skills if he included some statistical analysis. KT teaches a problem-solving methodology which enables an individual to handle problems successfully. By contrast the statistical skills allow the Circle to work as a team with great effectiveness.

ZD: There is minimal training for problem solving for supervisors and workers, aside from instruction in the proper use of the ECI form. The expectation is that either the supervisor will correct the problem identified on an ECI form or someone else will.

(34)

Writers, as widely different as J. R. R. Tolkien, Francis Schaeffer, J. M. Juran, George M. Prince and Prof. Y. Kondo recognize that creativity is a basic human (35)

right. Programs and procedures which challenge people to do their job creatively and give them the methods to do it will be the most successful and will do much to improve the quality of work life. Creativity cannot perhaps be quantified, yet such things as increased employee motivation and reduction of boredom and absenteeism are the kinds of effects a program of problem solving is likely to have. People need to perceive they have some control over their work even if such control is limited.

We are outsiders: we don't manage a factory nor do we work on line. But as outsiders, we have a perspective which can focus on strengths and weaknesses of the various procedures. A program which helps to sharpen a worker's skills and teaches him how to use them will have a high creativity quotient. When a person is better prepared to handle what comes to him in life, whether at work or at leisure, he develops more self confidence that he can participate in the control of his circumstances. KT and the QC Circle concept do these things. They recognize that people are problem solvers and that they need training to be effective. KT gives a logical, efficient method of breaking down a problem and arriving at a solution yet the procedure is flexible. KT is generally used on big, one-shot problems, but the technique can be applied in almost any situation. One strength this procedure has is that the problem-solver goes to the problem and lets it speak. Usually it is a single individual who uses KT analysis rather than a team; but there is no reason why a team cannot use this method to solve problems.

KT is designed for managers, though if a manager is people-oriented he will be concerned with those under him, that they also become strong problem-solvers. Consequently he will teach the KT analysis principles to his subordinates. (36)

The QCO concept emphasizes the statistical analysis of problem solving. Because it is a team effort, each member has an opportunity to contribute, to have his ideas accepted, to be creative, and so to develop self worth. Through the statistical analysis the team participates in the control over the work process; they are able "to close the loop", they can change what they are doing to what they are supposed to be doing. (37)

One of the strengths of the ZD program is that it covers the entire organization from management on down to the man on the line to make each person aware of his responsibility to do his job right. KT trains managers; the QC Circle trains supervisors and workers.

A caution we would post for the ZD program is one already anticipated by Dr. Juran. As long as the workers already have in their hands the proper training to do the job, knowledge of the process, and the means to change their actions or the process in order to conform to what is expected, a ZD type program can help motivate workers. (38)

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"ZERO-DEFECTS" - ALIVE AND WELL IN THE EASTERN EUROPEAN COUNTRIES

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INTRODUCTION

Back in the early 1960's a motivational program to raise product, process, and service quality levels, called zero-defects (ZD), swept the country. Unfortunately, in the author's opinion, it was mis-applied and, as fast as it swept up to great heights of recognition and application, it fell even faster into disrepute and discard as another "fad". However, the application of the ZD concept was not unique to the U.S.A. The ZD concept has been "alive and well" for some years in the Eastern European Socialist countries, and is currently enjoying a resurgence of recognition and application.

The author was informed - but was unable to verify the fact - that the ZD concept was applied at the Bata Shoe Company in Czechoslovakia prior to World War II. However, there is documentation to support the statement that a ZD concept was part of the Soviet Saratov System of Quality Control (1955), and part of the recent variant of the Saratov System, called the Lvov System of Quality Control (1967).

There has been a recent upsurge in interest in these two systems, and especially the ZD concept, as a result of the Communist Party Congress. At the February - March 1976 Congress of the Communist Party of the U.S.S.R., Mr. Breznev enunciated the "line" for the current five-year plan as "Raising Efficiency and Quality". The Parties of the other Eastern European Socialist countries adopted similar goals for their five or ten-year plans. The result has been a renewed interest in the Saratov and Lvov Systems and their implanted ZD concept.

THE SARATOV AND LVOV SYSTEMS

Space does not permit a full development of these two systems, but enough will be presented to give the reader an idea of the systems, and how the ZD concept inter-relates with them.

Of the two, the Saratov System is the older, having begun around 1955, as a movement to motivate workers toward better quality work, in the machine tool and engineering works in the Saratov region of the Ukraine (the System is named for the region where it originated). Its central idea was that all human activity, from design to selling and service, is the result of human work, and that the quality of the activity (resultant product or service) depends upon the quality of this work. In addition, it incorporated the idea that every worker is responsible for his/her quality of work, and the concept of self-regulation of quality (be the inspector for one's own work).

The System divided the product cycle into three stages - preproduction, production, and post-production. Then, for each stage and for the various type of workers at each stage, e.g., designers, technologists, production workers, inspectors, a criteria for defect-free work was developed. This criteria was the basis for the quality level indicator, which was essentially a measure of the percentage of defective work. These indicators were applied to various levels, e.g., individual, professional and trade groupings, stages (preproduction, production and post-production), factories, enterprises, industries and ministries.

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These indicators could also be based upon more complex measures than just the percentage of defective work. For example, the following eight factors made up one such quality level indicator:

1. Percentage of good product upon first submission.
2. Fulfillment of the monthly plan for the improvement of product quality.
3. Breach of technological methodology.
4. Loss from spoilage and scrap.
5. Product rejected by plant inspection.
6. Product rejected by inspections further down the stream of commerce.
7. Customer complaints.
8. Adherence to the "culture of work" (workplace conditions, general quality level of work produced, safety, morale, etc.).

The Saratov System became quite popular and soon spread to the rest of the Soviet Union, and to the other member nations of the Socialist Bloc. The Saratov System became known by the initials SBIP or BIP which stood for "Defect-Free Finished Product".

However, as the movement spread, variations began to appear. There appeared the Jaroslav, Minsk and Lvov variants in the Soviet Union, and other variations such as the Mlada Boleslav movement in Czechoslovakia, when a "home-grown" variety was desirable. These variations were in addition to changes made to the classical Saratov format. Of the Soviet variations, the Lvov System known by the initials SBT meaning "Defect-Free Work", and developed at a telegraph apparatus plant in the Lvov region of the Ukraine in 1967, is the most well known in Eastern Europe.

The reason(s) for the Lvov and other variations are varied, and to some extent unclear and confusing, because in some cases the updated Saratov System installations are difficult to tell apart. Some of the reasons for the development of the Lvov System, and its difference from the Saratov System were:

- A. The Saratov System was aimed more at manual workers - it was not broad enough in its coverage of non-factory workers.
- B. The Saratov emphasized "Defect-Free Finished Product", while the Lvov System emphasized "Defect-Free Work".
- C. The Lvov System developed a more complex, quantitative set of indicators for the quality levels of workers, Brigades, collectives, industries and ministries.

Both the Saratov, Lvov, Mlada Boleslav and other variant Systems are designed to be total Quality Control systems which have the ZD concept as one of their integral parts.

THE ZD CONCEPTS

The following are some of the characteristics of the ZD concept which these Eastern European Quality Control Systems have in common.

First of all, the system, especially the idea of "Defect-Free Work" and "Defect-Free Finished Product", was to be backed by the mobilization of all "forces" - the Party, the Labor Unions, the Ministerial Offices, the Management, the Collectives and the Brigades. The direction, including the determination of quality level standards and indicators to be maintained, emanated from the ministerial level.

Both moral and material stimuli were to be used. Moral stimuli consisted of such as patriotism - for good of Party and Country - and Socialist Competition - essentially striving for a first level rank among brigades, collectives, factories and/or industries. Material stimuli would take the form of positive and negative supplements to premiums or bonuses.

"Quality Days" were to be periodically held - once a week to once a month - when quality level indicators would be reviewed, and reasons for poor quality developed and analyzed for later correction.

An especially important aspect of the ZD approach was the potential that the worker had of attaining the level where he inspected and passed on his own work. Under the early Saratov System a worker that submitted defect-free work for a six-month period could attain the rank and title of "Self-Inspector" or "Self-Controller". This gave him the right to inspect his own work and pass it along without having to wait for the usual quality control inspector and inspection. It also provided him with a bonus of 10% of his pay. However, the "self-inspector" was subject to an audit about twice a month, and if found producing defective work, was subject to the loss of his rank and privileges, along with the bonus.

Under the Lvov and the more modern variants, the "self-inspector" concept was modified so that more people could participate. In this more modern version, a selected worker could voluntarily join the "Guild for Exemplary Quality" and assume the role of a self-inspector with a title such as "Producer of Exemplary Quality-Self Inspector". In return, the worker agreed:

1. To work in the spirit of good quality production.
2. Received a personal stamp with which all of his work would be identified.
3. Had the right to participate in meetings and discussions on scrap and defect control (as long as his own work wasn't being discussed).
4. Had the right to quick and complete information about the quality level of his work - especially rejected work.
5. The right to use the efforts and information of the quality control technologists.
6. Would receive a monthly bonus-varying from a percentage of base salary to a flat monthly amount.

This position was maintained as long as the worker continued to produce good quality work, as measured by the system's quality indicators.

The "self-inspector" would perform such inspections as he was capable of without special training or equipment - visual inspection, use of basic measuring tools, non-destructive tests. The work would then be passed down the line to where the technical control group, e.g., Quality Control, would perform the more rigorous inspections.

To aid in maintaining quality and assigning the responsibility for defects, a defect classification system, a defect list that also contained the party or parties responsible for the defect, and a daily posting of defects uncovered by inspection were used.

All new workers were indoctrinated in the concept of "defect-free work", and impressed with the thought of "Do it right the first time".

CONCLUSION

The application of the Saratov, Lvov, and other variant systems ranged from machine tool manufacturing industries to the food industries to research institutes. The concept of worker responsibility was pressed especially hard, and is reminiscent of the experience with ZD in the U.S.A. where "the tail wagged the dog" - ZD was thought to be superior to, and separate from, a good total quality control system, rather than as a tool to be used within the scope of a good quality control system.

With the current emphasis on Efficiency and Quality in the current five and ten year plans, the application of the ZD concept has not as yet reached its peak, so the time to evaluate the success of the movement has not yet arrived.

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THE PROBLEM WITH QUALITY

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INTRODUCTION

To deny that a problem with quality exists would force one to admit to reading no newspaper, watching no television, listening to no radio--or--purchasing no products or services. The famous industrial designer, Raymond Lowey wrote:

Americans are in a massive race to maintain our leadership against other nations in trade, training, goods and taste.

This is a fight. . .measured more in actions than in words, and one where our country loses a little each time any one of us lets his standards fall.

This fight is lost in 'little' ways--by faucets that leak. . . windows that rattle. . .windshield wipers that don't wipe. . . lights that flicker. . .zippers that jam. . .engines that smoke. . .containers that leak. . .flags that fade. . .by salesmen who are rude. . .by repairmen who are untrustworthy. . .artists and artisans who do their second best. . . by designers and manufacturers who think it doesn't matter just this once if they turn out products which are vulgar, shoddy and overpriced.(1)

When was this written? Yesterday? No. It appeared in June 1962. It sounds so familiar because the situation has changed very little. Consumers continue to have a problem with quality.

CONSUMER PROBLEM WITH QUALITY

The fact that every individual is a consumer who purchases products and services means that many millions of times each day there is an opportunity for a problem with quality. The exposure rate is quite high.

Think back to the last time you had a complaint about the quality of a product or service. What was the complaint? Was someone injured? Was there a failure to function the first time tried? Was the time-to-failure too short? Was the construction poor? Was the design inconvenient for use? Was the finish shoddy? Was the packaging inadequate? Were you treated discourteously?

Each of these possible complaints has a common element. Each represents a failure to meet your expectations. You had expected something; but were given less. At this point it is not important whether or not your expectations were valid. The fact is that these expectations do exist. This leads us to Business Quality Law No. 1.

Business Quality Law No. 1: If the customer believes that a product is of poor quality, the product is in fact of poor quality.

If a customer believes that a product is of poor quality, that consumer probably will not buy that product again. Furthermore, the customer may also cause the loss of additional sales through influence on relatives, friends and acquaintances. Thus, the poor quality results in a business loss even though the product met all of its drawing and specification requirements as evidenced by a thorough inspection.

Consumer expectations are higher today than they have been previously. Two major factors have contributed to these higher expectations. First, the massive aerospace programs with their rapidly expanding technology have created in the consumer an impression that "all things are possible". As new breakthroughs are announced, the consumer greets them with a blasé attitude of no surprise--it was expected. This posture has been transferred to even the ordinary products with which the consumer comes into contact.

Second, the "consumer movement" which was given considerable impetus in 1962 by President Kennedy's proclamation of the "Consumers' Bill of Rights", has grown into a major business. Where only a few years ago there was only the Better Business Bureau, there are now more than 300 Government consumer offices at state, county and city levels. Add to this the 31 federal agencies with consumer offices, 38 industry and private recourse groups, 6 national consumer organizations and 50 "Call for Action" programs at radio and television stations nationwide.⁽²⁾ This does not include the innumerable businesses who have added consumer relations organizations.

All of this means that today's consumer is increasingly bombarded with information and solutions on all manner of problems. The result tends to inculcate in the consumer the impression that whatever he wants, he can get.

The consumer's problem with quality is simply that products and services do not measure up to his expectations.

THE BUSINESS MANAGER'S PROBLEM WITH QUALITY

Like the consumer, the business manager's problem with quality is failure to meet expectations. However, unlike the consumer, the business manager's problem is a complex, multi-faceted problem requiring precisely balanced solutions.

The business manager's problem with quality can be described as a problem with Government regulation, product liability, quality sales losses, quality costs, or any combination of these factors.

Government regulations at the federal, state and local levels are having an increasingly significant impact on virtually every business. Requirements are placed not only upon products and services, but also upon the business systems which assure that the requirements are achieved.

Companies with contractual business with the Federal Government have been accustomed to both product and business system requirements. Product requirements are defined either in standards, specifications or in the contract. Business system requirements--especially those related to controls for product quality--are delineated in specifications such as Department of Defense MIL-Q-9858A, "Quality Control System Requirements"⁽³⁾ and National Aeronautics and Space Administration NHB 5300.4 (1B), "Quality Program Provisions for Aeronautical and Space System Contractors."⁽⁴⁾ Since these requirements are contractually imposed, the cost impact on the business is a determinable factor which can be negotiated.

A much different problem is faced by those businesses not producing products to contract, and are regulated by an agency such as the Food and Drug Administration (FDA), or the Consumer Product Safety Commission (CPSC). Both of these agencies regulate through Congressional mandates citing certain "prohibited acts" which are violations of the law. In the case of the CPSC, penalties are either civil or criminal. For businesses regulated by the FDA, penalties for violation of prohibited acts are criminal violations.

Both the FDA and CPSC have the authority to regulate product quality through product performance standards. The Consumer Product Safety Commission regulates the business system for quality control through "voluntary implementation" of a "Handbook and Standard for Manufacturing Safer Consumer Products."⁽⁵⁾ The objective of these guidelines is to

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to assist the manufacturer in developing business systems which will prevent the occurrence of prohibited acts.

The Food and Drug Administration takes a different approach by promulgating "Good Manufacturing Practices" (GMP) regulations for a class of products (foods, drugs, cosmetics, medical devices) and/or for specific products (candy, meat, prescription drugs). Violations of GMP's render a product "misbranded", and misbranding is a "prohibited act" subject to criminal penalties.

The manager of FDA and CPSC regulated businesses must consider the cost of compliance with the regulations in product pricing. The problem is not, however, straightforward since compliance would presumably reduce other costs such as product liability.

One of the most severe problems with quality facing the business manager is product liability. Since the doctrine of strict liability for manufacturers was upheld by California Courts in 1963, both the number of product liability suits and the amount of the awards has escalated. In 1965 the average award was \$11,644. By 1973 the average award had increased to \$79,940. In 1975 in Cook County, Illinois, the average award was \$144,091 and this excluded one judgement for \$5,000,000! (6) In virtually every case the products involved were cited directly or indirectly for poor quality which caused or contributed to a hazard.

According to a 1976 report (7), there were 20,000,000 injuries in 1973 which required medical treatment. Of these 110,000 resulted in permanent disabilities and 30,000 in deaths. Involved were some of the 11,000 consumer products and 360,000 manufacturing establishments. The estimated loss to the U.S. economy was \$5.5 billion.

Statistics such as these are startling, and would appear to add significantly to the problem with quality. However, caution is urged. When one considers the exposure rate--the number of people who use consumer products, times the number of products they use per day, times the number of uses per day, times the number of days per year-- a different picture emerges. Assume that the above injuries were sustained by 190,000,000 Americans using each of 10 products twice each day. This exposure rate results in an injury rate of slightly more than 0.001%! The business manager's problem with quality as it concerns product liability is how can cost effective controls be exercised which are so precise as to reduce an already low injury rate?

The business manager's problem with quality does not stop with the regulatory and liability impacts. The products or services being produced are compared in the marketplace with similar products and services. One of the major areas of comparison is how well does this product meet the expectations--the product quality--relative to similar products. If the product suffers in the comparison, sales will suffer. The business manager must somehow uphold product quality while at the same time holding down prices to remain competitive. The balance of these two factors can be extremely critical.

There is still another problem with quality which plagues the business manager. This is the constant pressure by managers and engineers in the professional field of controlling quality to add more inspectors, to buy more test equipment and to establish more and more sophisticated techniques on more and more areas of the business. The business manager is told that these things are essential to produce products with fewer problems with quality.

This escalation of the "quality control empire" is quite visible in many companies; and it is fostered by the regulators, by the liability threats and by the competition. The "value" of a program for quality control is too frequently cited as being self-evident. Rarely are the costs and risks estimated so that a meaningful management judgement can be made.

The business manager's problem with quality is obviously extremely complex. Unless the problem is solved--the product, the service or even the business may not survive.

THE QUALITY CONTROL PROFESSIONAL'S PROBLEM WITH QUALITY

The quality control professional is one who has developed an expertise in the techniques of measuring and controlling quality. It might be assumed that this class of individuals would have few if any problems with quality. Such is not the case.

One of the first problems with quality encountered by the quality professional is a conflict with the business manager. A measurement of quality indicates that a product fails to meet the requirements. The product is rejected. The business manager orders the product shipped, thus "over-ruling" the decision prompted by the measurement of quality. This can be a severe problem with quality, and has resulted in more than a few resignations of quality control professionals.

The business manager is responsible for the profit and loss of the business. Decisions regarding quality should be predicated upon not only the measure of quality; but also the business risks of shipping or not shipping a product which does not measure up. The answers to the two risk questions: "What is the business risk if the product is shipped?" should be based upon more than an intuitive judgement. Unfortunately, this is not always the case. The business manager may have a sound assessment of the risks of nonshipment; however, a knowledge of the risks of shipment, which are more technical in nature, may be meager. The quality professional who does not provide an estimate of the risk as well as the measure of quality, is contributing to the problem with quality.

Another of the quality control professional's problem with quality is the lack of management support for a program to control quality. Papers on this problem frequently appear in the literature and are presented at symposia. Corridor conversations at such meetings very frequently involve this problem. The typical cry is that management looks on engineering and manufacturing as contributing value to a product; but they look upon inspection and quality control as not contributing value to the product, as being obstructionists, or at best, as being a necessary evil. Management tends not to think of quality control as a part of the business. And the primary reason for this attitude is that many, if not most quality control professionals rarely think of their function in this context.

There are numerous indications of this "quality control is not a part of the business" attitude. There is constant pressure from both outside the business and within the quality control profession to keep the quality control function independent of other business functions such as manufacturing, engineering, marketing, etc. There is a tendency for quality control professionals to look at each new product regulation as a reason to expand the quality control organization. A look at the quality control organization in many companies will reveal a quality control empire where virtually all of the quality controlling functions of the business are snatched into this organization.

Quality control professionals frequently talk cost savings; however, when asked for specifics--when asked if the value of a quality controlling function exceeds the cost--respond with glittering generalities and "motherhood" statements.

Quality control professionals do have a problem with quality. Unfortunately, too many quality control professionals are a part of the problem with quality.

TOWARD A SOLUTION OF THE PROBLEM WITH QUALITY

A solution to the problem with quality can only be achieved through action--action on the part of the consumers, business managers and quality control professionals. The following are some of the actions which should be taken:

Consumer Action

1. Recognize that, as a consumer, your problem with quality is simply that expectations have not been met. Determine first if your expectations are realistic. You can place your expectations in three categories:
 - a. Realistic - the actual must be changed.
 - b. Unrealistic - the expected as claimed (advertising, salesmen, etc.) must be changed.
 - c. Unrealistic - the actual meets the expected as claimed; but still is too low.
2. Complain first directly to the business involved. The odds are in your favor that you will get satisfaction on the first attempt. There are techniques for complaints which will enhance your chances of satisfaction. These techniques are very well-described in "Complaint Power"⁽⁸⁾, a 24-page publication of the Maryland Center for Public Broadcasting Consumer Survival Kit award-winning program now in its fourth season. The recommended steps are:
 - a. Be sure the complaint is justified.
 - b. Decide what action you want.
 - c. Contact the person who has the authority to make the decision you want.
 - d. Keep the tone business-like.

Unfortunately, too many consumers complain to everyone excepting the business involved. The businessman deserves to hear your complaint from you first. In most cases, you will get satisfaction. However, if the businessman fails to respond, do not hesitate to utilize the many other resources available to you.

Business Manager Action

1. Respond to each customer complaint promptly, in a business-like manner and with positive action, where feasible. If action cannot be taken on the customer's problem, inform him of the reasons. If action must be delayed, inform him of when it will be taken. Remember, action can be taken to change either the product or service, or the expectations.
2. Examine your product literature and advertising for statements which tend to over-inflate the customer's expectations. Periodically audit sales talks for inflated claims.
3. Consider your quality control function as an integral part of the business. Insist that standards realistically match customer expectations, and avoid "perfection" as a standard. Require quality control managers to show that people, measuring equipment and procedures do in fact reduce long term costs.

Quality Control Professional Action

1. Think of your function as an integral part of the business. Apprise those with profit and loss responsibility of the risks, as well as additional personnel, equipment and procedures.

2. Avoid adopting a new program developed by a source outside your business, unless that program can be shown to decrease long term costs for your business. Such programs include sampling systems, motivation programs and methods to specifically meet regulatory or other requirements which may not be appropriate for your business.
3. Work constantly to achieve consistent agreement of actuals with expectations by assuring that realistic standards are set and enforced at all levels of the business process.

In Conclusion

If we as consumers, business managers and quality control professionals work on both the actuals and the expectations to make them more nearly equal, it will not be long before the words of Raymond Lowey cited earlier will no longer be true. When that happens, there will be no problem with quality.

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LCS 020:10:000

QUALITY, MANAGEMENT AND YOUNG ENGINEER

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ABSTRACT

Most graduating engineers entering the field of quality assurance face five basic problems in an industrial environment with respect to achieving quality in the final product. These problems are: (1) A young engineer is apathetic toward a quantified decision making process, (2) He practices the principle of interocular trauma in handling his assignments, (3) He lacks an understanding of variation in identical units of the same product, (4) He has a built-in zero error attitude in his decision making process, (5) He lacks business communication skills. This paper discusses (1) the sources of these problems and (2) the relation of these problems to the quality of products.

It is essential for management to recognize the existence of these basic problems, to understand them and to apply solution methods which will motivate young engineers to overcome them. A motivational approach advocated in this paper includes: (1) providing opportunity to young engineers for training in applications of statistics to decision making, oral communication and written communication (2) communicating to engineers that overcoming these problems means success (3) providing periodic performance reviews with respect to progress on these problems. A case history approach is used to illustrate how to accomplish recognition, understanding and solution for each of the five problems. Case histories cover consumer industries, government contracts and OEM/supplier situations.

The paper further discusses the consequences if these problems are not recognized or if they are recognized and nothing is done to overcome them. In either case, management should be concerned with the cost and dangers resulting from inadequate recognition of product quality deficiencies. Each area of corporation vulnerability is identified and the consequences are discussed.

LCS 670:70:000

PRODUCT QUALITY IMPROVEMENT THROUGH "VISIBILITY"

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SUMMARY

A practical approach for improving product quality is by means of quality visibility and employee quality awareness programs. Using Northrop Corporation Defense Systems Division as an example, this paper expresses the conviction that people excel in task performance beyond expectations when given proper management attention, a clear understanding of the requirements, adequate resources and timely measurement of performance.

By advocating, implementing, and maintaining an Employee Quality Awareness Program and a Quality Visibility System, a significant product quality improvement has been reached at the Defense Systems Division (DSD).

This end has been accomplished through innovative systems that:

- provide continual quality awareness;
- develop a spirit of competition among small organizational groups;
- provide recognition of group endeavor;
- instill a feeling of personal achievement within the individual;
- involve all levels of management;
- provide visibility to all through a centrally located Visibility Center;
- force timely implementation of corrective action through open display of adverse trends as associated with specific responsibilities.

GENERAL

The concept of quality visibility (originated at Northrop Aircraft Division) and awareness (originated at Northrop Defense Systems Division) was conceived to induce a team action in the production of hardware that is superior in quality and reliability.

In the usual concept of quality control, defect and/or test data are gathered and circulated by periodic reports which are sent to management personnel of the affected areas, or a chart room (war room) is maintained as a display for top management personnel only.

In either case, the effective response is often negligible. The report is discarded and the war room charts scanned and ignored if they do not contain a clearly defined responsibility.

Under the quality visibility and awareness concept however, quality status, cost impact problems, and corrective actions require the responsibility to be defined. Process area charts (areas of responsibility) are displayed in the Visibility Center so that they may be recognized as to responsible individual as well as to the individual contributor to the quality status of the area.

Quality awareness is achieved through a continuing effort by management to recognize team and individual achievements.

DSD's Visibility Center and Awareness Program were implemented in 1976, based on the premise that when given proper attention, a clear understanding of the re-

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quirements, adequate resources, timely measurement of performance and recognition of contribution, people excel in task performance beyond expectations.

Since its inception, this program has proven employee team performance in the manufacture of a product that is cost effective and superior in quality and reliability. DSD's record of accomplishment is a direct reflection on the skills of individuals who have a personal interest in team performance in the production of quality products.

OBJECTIVES

Knowing that motivation influences productivity, implementing a program that would make the best use of proven techniques was a prerequisite. We invoked a number of motivational techniques such as job enrichment, team competition, recognition of team and individual effort, reward, and participation by all employees in the decision making loop.

To these was added a program or series of programs that provided an awareness of quality and the rationale for its need.

Identification of process area responsibility is maintained in the Visibility Center as well as on individual floor charts. Although this method may give an area supervisor undesirable exposure, if his area of supervision has an unfavorable defect trend, yet it may provide a desirable stimulus by the exposure and natural competitive spirit induced between the supervisors of the various process areas.

In order to meet our objectives, it was necessary to provide an effective system that would collect and display manufacturing performance data and provide a continuous quick response to effect corrective action when needed and employee recognition when warranted.

To provide the visibility and the management involvement required to assure quality awareness, a central area open to all employees was of paramount importance. This center would maintain displays of Manufacturing and Procurement quality status, cost impact problems, and corrective action follow up as related to a specific manufacturing and procurement operations assigned to a Manager or Supervisor responsible for their administration.

In order to maintain quality levels necessary to provide quality goods to our customers on a cost effective basis, controls had to be published.

KEY ELEMENTS

The following key elements are necessary in order to provide a continuing long-term level of quality within the organization:

- A. All levels of management must be involved. Top management must not only have a sincere interest in the level of quality, they must also actively participate in effecting corrective action at any level. They must also be involved in the recognition phase to provide stimulus at the craft levels.
- B. Manufacturing and Quality organizations must work together to provide continuous process control.
- C. A systematic approach for establishing acceptable quality performance published goals based on process capability.
- D. A centralized data display for the use of management and elucidation of the work force.
- E. Timeliness of collection, analysis and utilization of data are imperative for an effective corrective action response.
- F. Division of the work force into discrete work unit or process group quality achievement teams, and suitable displays of group performance to stimulate quality awareness and a competitive spirit.
- G. Recognition must be a continuing effort, equitably based on achievement.

ADMINISTRATION AND DIRECTION

The program is best administered by the Quality Engineering organization.

The program administrator is responsible for the operation of the Visibility Center, the establishment of goals and limits, and determination of contest winners, and duties associated with the maintenance and housekeeping of the center itself.

The overall direction of the Visibility Center is a function of the managers responsible for the administration of specific programs within Procurement, Manufacturing Operations, and Manufacturing Support. It is the function of Quality Engineering to provide the support to the user organizations in order to comply with their specific needs.

MECHANICS OF OPERATIONS

Data Collection

Data are derived from inspection records, test results, and material review actions generated by workmanship related causes.

Defect data used as a basis for determining process capability are collected from the inspection points and are screened to determine workmanship-caused defects. Workmanship defects are then equated either to units built, earned standard hours or to whatever base provides the most suitable common denominator. If the process is large enough, it may be divided into several groups or team units, and direct comparisons can easily be made. However, if the processes are different and the complexity has wide variations, a suitable common denominator must be derived and an adjustment factor utilized to account for the variance in complexity. Process capability established through workmanship history is the basis of the Quality Visibility and Awareness Programs through stimulation of team competition. Quality awareness is promoted in a subtle manner through recognition derived through visibility and quasi-promotional programs which are discussed later in this paper.

Defects that caused problems in which material review actions were necessary are utilized in employee performance measurement. The expense incurred, because the hardware is not reworkable to the drawing, is also highlighted in order to effect corrective action when needed and to emphasize the cost impact created by catastrophic defects.

As a measure of product quality, attribute test data are collected in terms of yield. Yield is preferred to rejection rate solely on the basis of presenting a positive profile. Yield data is used to signify trends and key corrective actions if indicated through tracking of specific assemblies or classes of hardware, i.e., continuity testing versus functional testing.

Data Display

Data are displayed in the Visibility Center that reflect trends in workmanship effectivity. Defects are plotted against unit gain with statistically determined control limits coupled with an adjustment factor to force improvement. Penetration of the control limit triggers problem analysis, identifies cause, and delegates corrective action requirement with effectivity commitment.

This is a means to assure positive response to an undesirable trend. Effectiveness of corrective action is accepted only through a positive reversal of the process trend.

Data relative to test results, receiving inspection activity, material review board action, and scrap and rework cost impact are also maintained and displayed in the Visibility Center for use by the concerned responsible managers. See figure 1.

MANAGEMENT PARTICIPATION

The primary element to the success of the Quality Visibility and Awareness Program is the support and participation of all management levels. The support of top management is essential in assuring response and participation of all levels of management.

Figure 1.

Management participation usually occurs at three levels. Firstly, there is a daily review of individual operator performance by first-line supervision which is accomplished by review of the inspection sheets. The review serves a twofold purpose, namely, it keeps the supervisor informed of the types of defects and problems incurred, and provides an assessment of each operator's performance.

Secondly, middle management and first-line supervision conduct weekly meetings in the Visibility Center to review quality status and to discuss corrective action commitments.

Finally, weekly review of quality status and a follow-up of missed corrective action commitments are functions of upper level management.

QUALITY VISIBILITY CENTER PROCEDURES

Awards and Recognition

Manufacturing operations are divided into competitive units designated "Manufacturing Quality Achievement Units". These units perform either as sub-groups within their assigned work centers or as units representing a unique work cost center or process. Each unit is in competition with all other units, for the purpose of improvement recognition. Each unit has a visibility chart on display in the Visibility Center as well as a three-quarter size version on the unit supervisor's desk in the work area.

The program is divided into monthly periods; the periods end with the last full work week of each month. Personnel comprising the "Unit" include the supervisor, employees who have participated within the unit for a least three weeks of the competition period, and material control support personnel. The unit supervisor is responsible for determining eligibility. All units are eligible for a recognition award in each competition period.

The program administrator is responsible for providing adequate traceability on achievement unit visibility charts to identify unit achievement.

The monthly award selection is based on the highest percentage of IMPROVEMENT (reduction) of defect rates. A degree of complexity factor based on past performance is determined and is used to adjust the performance ratios between units of dissimilar processes.

AWARENESS

In order to promote employee Quality Awareness, the following methods have been utilized:

- A number of illuminated signs are placed in strategic locations throughout the plant. Each sign displays different quality messages throughout the year.
- Each monthly publication of the company organ carries a quality slogan as well as a photograph of the monthly award ceremony complete with story and names of the recipients.
- The company pay envelopes are utilized periodically to convey messages and pamphlets on quality to each employee.
- Special awards and citations for exemplary performance are given with suitable recognition in the company organ.
- The trophy awarded the monthly Quality Achievement Award winners is displayed in the work areas of the winners.
- An Honor Roll of past award winners is prominently displayed in the Visibility Center.

Data Collection

Workmanship performance is measured through a count of operator caused defects which are management controllable, based either on units built, chances for defects (complexity), or defects per earned standard hour.

For competition purposes, inspection decisions are considered final; however, each of the area supervisors has appeal channels by daily review of inspection reports.

Defect Charting

Defect rates and material review actions are plotted to reflect performance levels at the lowest practical process level.

Simply, inspection results are plotted on modified p-charts with respect to process areas.

There are several significant areas used in the Northrop DSD visibility concept. First, a modified control limit is used, based on the average established by the process with a committed improvement factor included.

Second, a weighted average is plotted, where the weighting is based on datum age and portrays the greatest significance when recent. This is a smoothed average and will be explained later in greater detail.

Third, in the usual applications, the limits and defect averages are recorded and maintained in the office or in reports reviewed only by interested management and quality control staff.

Computation of Control Limit Lines

The control limit line is a mathematically established performance standard that, if penetrated or jeopardized by the cumulative average, triggers problem analysis and appropriate corrective action. Control limit lines are established on the basis of the following formula to determine the natural process limits:

$$\text{Control Limit Starting Point} = \bar{C}_1 + 2(\bar{C}_1)^{1/2}$$

As a matter of preference and control, a two-sigma limit is used as the starting point. The line slope defines the percentage of imposed improvement.

Control limits are subject to periodic adjustment based on the most recent performance. If the adjusted limit start point is less than the end of the previous limit, the same percentage of improvement for the slope will be used for the new period. If the adjusted limit start point is greater than the end of the previous limit, the existing limit line will be extended horizontally for the next period.

An exception to the rule is a management prerogative that permits raising of the limit based on significant uncontrollable influence on the process such as skill level changes, etc.

Control limits are not used to indicate an acceptable performance, but as a goal to stimulate improved performance and as a problem analysis triggering function.

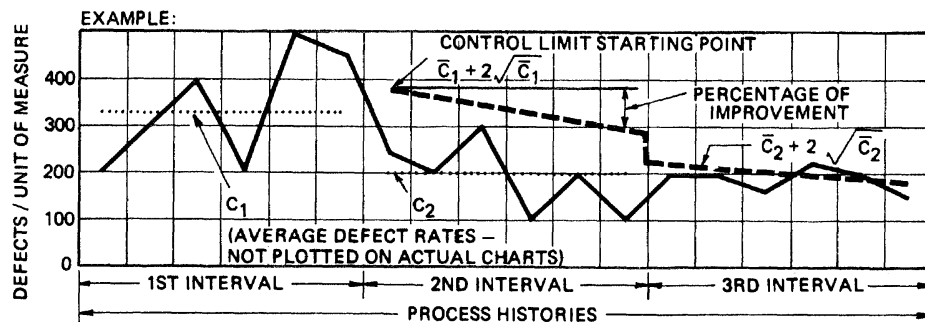


Figure 2.

COMPUTATION OF TREND LINES

Computations of trend lines for this purpose are accomplished by using a moving average and a technique called "triple smoothing". This is a standard process that, when used on a computer, uses much less computer space than ordinary moving average computations.

The outstanding advantage of this triple smoothing method of computation is that more emphasis is placed on recent data and less emphasis on older data. This tends to suppress random variations, which is not the case with ordinary averages which consider all data equally.

Weight functions and response characteristics of ordinary averages comparable to triple smoothed averages, based on a six-unit ordinary average, are the following:

Ordinary Average

A single large datum will cause a sudden increase when it is included and also a sudden decrease when it is removed.

The effect on the average by the inclusion of a large datum may partially correct or reverse the average when removed.

Any given datum is given maximum weight when included, which is maintained until removal, when the weight reverts to zero.

Triple Smoothed Average

A single large datum entry will cause a smaller sudden increase when included and no sudden change from then on.

There are no cancelling or reversing effects.

A given datum is initially given a reduced weight and then an increased weight for the next two time units. The weight effect slowly decreases as the datum age increases, approaching but never reaching zero.

Smoothing averages are computed by recursion. Initial estimates are used to start the computing process. The estimates can be ordinary averages, etc. For this application, ordinary averages of six units of data are used to begin the process. However, the initial estimate is satisfactory, as inaccuracies will be insignificant beyond six units of recursive updating.

Triple smoothing uses three computations, called triple pass smoothing. A , A' and A'' are averages from the first, second and third passes respectively; the subscript "o" denotes the old average, the subscript "n" denotes a new average and X_n is a new datum to be included; "a" is the weighting factor.

$$\begin{aligned}A_n &= A_o + a(X_n - A_o) \\A'_n &= A'_o + a(A_n - A'_o) \\A''_n &= A''_o + a(A'_n - A''_o)\end{aligned}$$

The old single pass average A_o , the old double pass average A'_o and old triple pass average A''_o must be maintained between updates. A''_n is used for charting or comparison purposes. The constant "a" has been selected as 0.5 to provide the desired response.

When "a" is 0.5, the triple pass computation can be reduced to the following:

$$\begin{aligned}A_n &= \frac{A_o + X_n}{2} \\A'_n &= \frac{A'_o + A_n}{2} \\A''_n &= \frac{A''_o + A'_n}{2}\end{aligned}$$

PROBLEM IDENTIFICATION

The Quality Visibility Center analyst identifies problems requiring corrective action based on analysis of defect causes. The analysis is focused on work centers where an unfavorable sequence of data points either approaches or penetrates the control limit. This condition demands an action item requiring corrective action and a committed effectivity. Confirmation of problem resolution is determined by a favorable trend reversal.

Manufacturing supervision may identify problems through their review of Production Inspection Reports, area surveillance, or from knowledge of their respective work areas.

CORRECTIVE ACTION

Each problem requiring correction is placed on an Action Item chart, relative to the work center affected. It is keyed to the Defect Trend chart with a colored indicator. Colored indicators reflect the problem, the area of responsibility, and the status. The Action Item chart defines the problem, the corrective action, and the committed effectivity.

The Corrective Action engineer effects corrective action by issuing a Notice of Corrective Action Requirement (NOCAR) assignment or placing the problem on the agenda of the Corrective Action Board (CAB) as necessary. The NOCAR is an instrument to assign responsibility for action and commit effectivity. The CAB is a board made up of the responsible managers with the authority to implement corrective action throughout the organization.

The Visibility Center coordinator follows up on all missed effectivity items, to assure that the next higher level of management is aware of the problem, and commits for corrective action.

In the event of a second missed effectivity, the Visibility Center coordinator submits the problem to the Corrective Action Board for review by the responsible managers.

AVERAGE COMPARISON: ORDINARY VS SMOOTHED

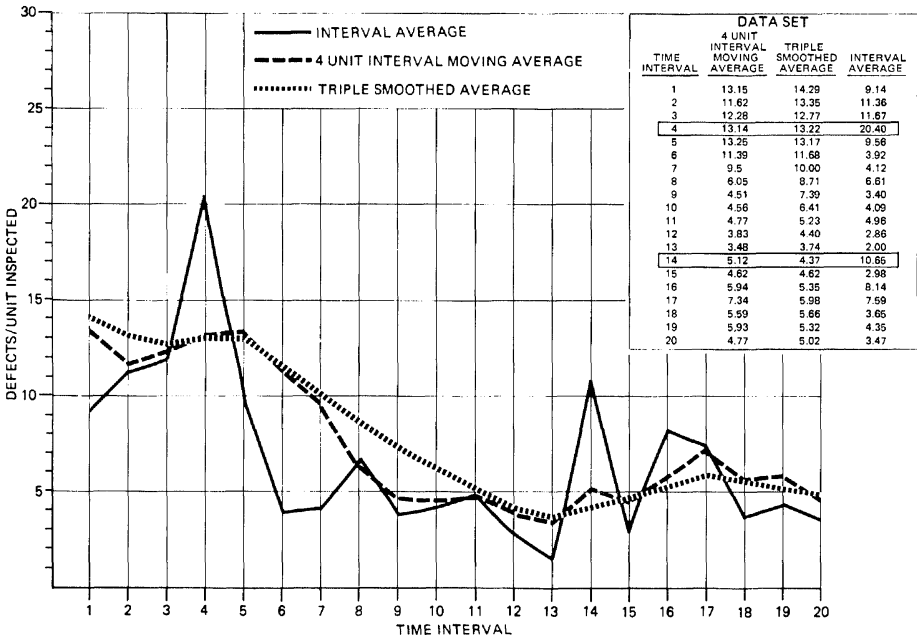


Figure 3.

MEASUREMENT OF SUBJECTIVE VARIABLES

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Unambiguous definition of product characteristics is essential for specification of process control limits, monitors, feedback, control and corrective action systems. Most engineering data are measurable with physical instruments assisting establishment of reliable processes.

In many instances product characteristics are assessed by response to sensory stimuli, e.g. taste, odour, appearance. This paper considers methods of measurement of these subjective quality factors. Discussion is restricted to appearance assessment although the underlying principles are usually applicable to other sensory measurements.

THE PROBLEM

In the absence of definition of appearance by physical metrics quality control relies upon a mental perception of "good" and "bad". Although the reject criteria may be supported by illustrative samples, mental interpretation of the standards can vary with individuals dependent on the relative weightings applied to the many surface components contributing to visual sensation.

Process evolution tends towards minimizing defect frequency; the ideal system having a near zero probability of producing non-conforming material. Processes falling short of this utopian state generally require inspection monitoring to determine whether the system is in control and to segregate non-conforming material. The disadvantages of this method lie in the cost, post-hoc nature of the control system and variability in human response.

Disagreements can develop in which a customer determines that material is unsatisfactory while the supplier believes that is of normal quality. Both parties consider themselves a victim of a change in standard on the other's part. A decision to improve quality in future shipments generates stress in the production system which now has to adjust standards to an ill-defined level.

Two potential solutions are evaluation of instrumental methods of defining surface appearance or control of process so that the product automatically satisfies the end use. The problems involved in development of instrumentation will be considered together with experimental methods for assessing the interrelationship of process variables and visual appearance. Data collection from designed experiments is simplified by the existence of a physical measuring system but is not dependent upon it. The methods of analyzing sensory reactions will be discussed.

DEVELOPMENT OF INSTRUMENTS

The visual impression of a surface is influenced by a variety of conditions rather than one single fact. Displeasure reactions may occur when a single condition exceeds a threshold value, through non-uniform distribution of a surface factor or due to coexistence of several imperfections at intermediate levels. Therefore a basic criterion for a measuring system is capability of determining intensity and distribution of several surface elements. This is far from a simple task requiring that each surface component is identified and a method of measurement evolved. Such data are valueless unless they can be correlated with human like-dislike judgments. Thus a psychological scale is also necessary.

Psychophysics, the branch of psychology devoted to measurement of human response to stimuli, originated with the German psychologist Gustav Fechner (1801-1887). Fechner hypothesized that a psychological ratio scale could be developed based on discovering a threshold value below which a stimulus is not perceived and a unit of measure, equal to the minimum detectable change in stimulus intensity - referred to as "just noticeable difference". Manning & Rosenthal⁽¹⁾ have published an elementary text describing the concepts and principles expounded by Fechner.

Much of the early work was devoted to assessing response to monatonic variables which were measurable instrumentally, e.g. discrimination between light intensity or difference between two weights. The problem becomes more complex when several factors contribute to value judgments. The difficulties in scaling under these conditions are discussed in the literature, for example Torgeson⁽²⁾, Coombs⁽³⁾, Edwards⁽⁴⁾, Swets⁽⁵⁾ and Galanter⁽⁶⁾, leading to the conclusion that psychological scale development is a very lengthy and costly process.

The feasibility of economic development of instruments to measure appearance is low considering the dual difficulties of constructing metric devices and psychological scales. Thus the best instrument currently available is human - the inspector.

VISUAL INSPECTION

A trained inspector has many attributes of the ideal measurement and contour system, being equipped with a detector system, the eye; an interpretive component, the brain, capable of storing, comparing and making decisions based on the signals received from the eye; a feed back system either auditory or mechanical and ability for removal of substandard material. Deficiencies of the inspector are lack of consistency in decision and occasional failure to respond to a defect signal.

Jerison and Pickett⁽⁷⁾, following work by Holland⁽⁸⁾⁽⁹⁾, suggest that two processes are involved in an inspection task, a decision to observe and a decision to respond to a signal. Thus attention span and response decision determine inspection efficiency.

Vigilant research is frequently interpreted in terms of Signal Detection Theory (SDT). Mackworth⁽¹⁰⁾ presents a comprehensive review of the work in this field while Baker⁽¹¹⁾ discusses SDT application to analysis of Q.C. Performance.

In any inspection task one of four states exist:

- (1) Defect present, inspector rejects - a hit
- (2) Defect present, inspector accepts - a miss
- (3) No defect present, inspector passes - a hit
- (4) No defect present, inspector rejects - a false alarm

SDT strives to explain the occurrence of hits and false alarms.

Tanner and Swets⁽¹²⁾ suggest that a stimulus impinging on a sense organ changes the average value of some quantity which is ranging randomly within the brain. This neural process has a mean of zero when no signal occurs, and a non-zero value when a signal is received. Oscillation in the neural system will occasionally cause a critical non-zero value to be exceeded in the absence of a signal, giving rise to a false alarm. If the neural system is close to its low point, when a signal is received, the accompanying system change may be insufficient to exceed the critical response value, giving rise to a miss.

Under the hypothesis that neural oscillations are normally distributed and the addition of a signal causes only a displacement of the mean, the model can be portrayed as two normal distributions with equal variance and means separated by a distance equal in magnitude to the intensity of the stimulus expressed in terms of standard deviations. If the separation of the means is such that the distributions overlap, misses and false alarms will occur. The probability distribution of hits, misses and false alarms are computed from the degree of overlap.

The probability model, thus developed, implies that an individual has an innate sensory discriminating power, a function of the standard deviation of neural system oscillation. This would suggest predictability of hits and misses, in overlapping distributions, with the central tendency of the pass-reject criterion being the intersection of the distributions.

Swets et al⁽¹³⁾ suggest that the monitoring task involves a decision in addition to discrimination, yielding two values d^1 and B. Discrimination (d^1) is a function of the separation of means between the noise and noise plus signal distribution and measures sensory capability. The decision involved in establishing a signal criterion (B) is a measure of the caution of the observer. The value of B is influenced by many factors. Smith⁽¹⁴⁾ describes how a single word from an authority

figure can change the proportion of product passing inspection. Criterion is a variable reflecting many influences, particularly those related to perceived rewards of making a "correct" judgment and the cost of making errors. Criticism for releasing defective material usually leads to an increase in the false alarm rate.

Baker⁽¹¹⁾ summarizes factors enumerated by Colquoun⁽¹⁵⁾ and McKenzie⁽¹⁶⁾ which affect inspector decision but omits the vital aspect of expectancy.

There is ample evidence that the expectancy of an observer influences his stimulus response, as illustrated by the following case histories.

Case History I

A process, in early stages of evolution, consistently exhibited a defect rate in the range 8 to 12 percent. After the cause was isolated and corrective measures instituted, a marked drop in defect level occurred but exceeded the level predicated prior to implementation of the changes.

Investigation determined that the majority of defects were restricted to lots examined by a particular inspector. Re-examination of rejected material by the inspection foreman showed that the majority of rejects actually conformed to standard.

The inspector was surprised that the foreman disagreed with the original disposition decision and thought his decision was right "because we always get about 10 percent defectives with this material."

Whatever connotation is placed on the mental process motivating the inspector's action it is evident that the criterion applied was based on his expectation that one tenth of the material was unacceptable.

Case History II

The actors are four engineers and technicians, each having extensive experience in assessing surface appearance of aluminum extrusions.

A test was being conducted to assess the validity of the hypothesis that above a threshold level increase in an impurity level caused progressive deterioration surface finish. The threshold was not defined accurately but predicted to be within a specified range.

The experimental design (discussed later) consisted of extrusion of groups of ingots containing levels of impurity ranging from close to zero to an order of magnitude above the upper bound of the expected threshold. Extrusion order of each group was randomly assigned, each experimental group being interspersed with a like size batch of control ingot.

Subsequent analysis of samples from the experiment showed no significant difference between the surface finish of any conditions tested. However the behavior of the observers during the test is instructive.

Extrusion sequence in the early stages of the experiment was:

- (1) Control
- (2) Impurity in threshold range close to lower bound
- (3) Control
- (4) Impurity below lower bound of threshold
- (5) Control
- (6) Maximum impurity content

As the test proceeded each observer noted that group 2 was essentially the same as group 1, leading to the conclusion that the threshold level had not been reached. Group 4 was similar to control groups, an expected result. While group 6 was being extruded the observers became more attentive, heads moved towards the product which received close scrutiny.

Subsequent questioning showed that each observer went through similar thought processes illustrated by the following sequence table.

Stage	Time	Reactions and Thoughts
1	Immediately prior to extrusion of group 6	We will now see a marked deterioration in quality
2	Extrusion of first ingot group 6	Looks same as control - probably too early to see anything yet - probably show up on next ingot
3	Extrusion of second ingot group 6	Still looks good - deterioration must be less than expected, must look harder
4	Extrusion of subsequent ingots	As I look harder I can see something I did not see in previous ingots. I think it is worse - but not as bad as I thought it would be

While in reality there was no significant difference between group 6 and preceding groups, expectation of a deterioration caused more intense scrutiny to the extent that features, overlooked in previous material, became noticeable and classified as defects. This is a clear example of expectancy changing the decision criterion.

Maintenance of a consistent decision criteria relies upon retention of a mental picture of a visual standard. Thomas⁽¹⁷⁾ found that experienced inspectors acquired an image of good material against which defects were highlighted. However it is contended that the mental image is subject to variation. The following adds credibility to such a hypothesis.

Case History III

In two series of experiments control ingot, selected randomly from the same population, was compared with experimental material, treatments applied to which differed between the series. Three experienced observers witnessed each run in both experiments.

Prior to the final examination of samples all observers agreed that in the second series the surface appearance of the material produced from the control ingot was significantly worse than observed in the first series. When the coded samples were compared it was clear that the control material from both sets of experiments came from the same appearance populations.

The difference between the observers' impressions and reality probably resulted from differences in contrast between the control and experimental material in the two tests. In a paired comparison test the control material was invariably better than the experimental material in test 1 but in test 2 there was considerable overlap in the appearance distributions of the control and experimental sets.

These observations suggest that contrast in appearance in the first test resulted in suppression of signals emanating from the control group. Because the surface appearance of all material in the second group was very similar, more intense scrutiny was required to differentiate between the control and experimental material. This caused unconscious increase in observer attention revealing small imperfections in the control group unnoticed in the first series, leading to the conclusion that the control had a worse finish in the second series than in the first.

It can therefore be reasoned that an inspector is likely to accept substandard material which is close to specification limit if the preceding material contained gross defects. Conversely, conforming material may be rejected if preceded by high quality.

The post-hoc nature of inspection, coupled with inspector variability and cost, are driving forces for automatic control of factors leading to rejectable material. Identification of these parameters are best achieved through designed experiments; however such methods present challenges in both determination of the experimental format and in measurement of response - surface appearance.

EXPERIMENTAL DESIGN

Determination of the format and size of an experiment necessitates consideration of characteristics peculiar to the test procedure, the method of obtaining data and the type of result being sought. Once these factors have been established standard references on experimental design such as Davies⁽¹⁸⁾, Mendenhall⁽²⁰⁾ and Cochran and Cox⁽¹⁹⁾ are useful in determining the most efficient manner of obtaining the necessary data.

In many metal working processes tool-metal interaction causes formation of boundary layers which influence appearance. Frequently the nature of this film and consequently the quality of surface of the formed material is influenced by characteristics of the material being processed. Change in the material passing over tooling may not be accompanied by an immediate conversion of the boundary layer which may pass through transition phases before the characteristic layer of the new material is fully developed. Thus sufficient material must be processed to ensure complete transformation before appearance of a patch is judged.

Time dependent changes influence product appearance in many processes due to factors such as tooling wear. Where such trends are known to occur or are highly probable, the sequence of variables being evaluated should be balanced with respect to time.

The method of evaluation must be designed to minimize errors resulting from contrast effects and observer expectancy discussed previously. The first of these considerations dictates that data should be obtained from samples rather than from observation during the experiment.

To minimize expectancy judges must be ignorant of the treatment employed which is best achieved by presentation of coded samples in random order.

There are four basic methods of judging surface finish: magnitude estimation, rating by standard, ranking and paired comparison. The first two of these are highly error prone.

In magnitude estimation the subject is presented with samples one at a time and is asked to rate it on a numerical appearance scale. We have already seen that the magnitude of any judgment will be influenced by the items just previously examined. In addition, Miller⁽²¹⁾ concludes that the average subject can categorize correctly into somewhere between 5 and 9 categories irrespective of the sensory dimension of the experiment.

Rating by standard entails use of a number of standards spanning the range. The subject is presented with samples one at a time and asked to identify the pair of standards which bracket his subjective reactions. One difficulty with this procedure is that if the difference between adjacent standards is small enough to ensure adequate separation of the items into homogenous groups, different observers are certain to disagree with the order of the standards.

Ranking requires that the panelists place all samples in a progressive array from worst to best. This method has the advantages that the subject compares samples rather than relying on a mental image. In addition the rating is determined by the subject.

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The number of comparisons required for positioning a sample are few in the initial stages of ranking but increases rapidly as the process continues. Thus ranking of large numbers of samples is tedious and time consuming. The time taken by five observers to rank 72 samples from an experiment varied from 150 minutes to 260 minutes. Under such conditions vigilance decrement, first enunciated by Mackworth⁽²²⁾, is highly probable leading to misranking of some samples. The resulting reduction in accuracy of the data is unlikely to have serious consequences in experiments containing several replicates of each factor. Displacement of a sample from its "correct" rank is probably small if the ranking of several inspectors show highly significant coefficients of concordance and rank averages are used.

Data from ranking tests can be used for analysis of variance providing the dangers of applying parametric tests on non-parametric data are appreciated. Output of such analyses can be used to determine which factors influence the measured response but cannot be used to obtain estimates of magnitude of differences. This metric can however be estimated by paired comparison.

In paired comparison testing two samples are presented and the subject asked to express preference for one over the other. Doehlert⁽²³⁾ discusses various strategies of testing which range from evaluation of all possible combinations of pairs to designs in which each judge sees fewer pairs arranged so that the combined data for all judges include every pair an equal number of times. Several techniques are available for data analysis which are referenced by Doehlert.

The major advantage of paired comparison is that the subject does not have to rely on previous responses or scoring systems. In addition, each response requires only one decision in a forced response situation. This increases the probability that "wrong" results occur only when samples differ by an amount which is not much in excess of the discriminating power of the subject.

On the negative side, a balanced design involving comparison of all possible pairs requires $n(n-1)/2$ observations to generate one data set. Since most evaluation schemes presuppose a number of judges, each judge performing the test a number of times, the method becomes cumbersome unless the total sample size is small.

Undoubtedly there are situations (e.g. taste testing) in which these methods are justifiable. However in appearance evaluation such detailed analysis is frequently unwarranted because the finished product does not receive anywhere near the same degree of scrutiny as is required in making a decision between two samples.

An ideal solution is to combine the simplicity of the paired comparison evaluation but reduce the amount of testing necessary to obtain a reliable result. Doehlert suggests method in which three or more items at a time are evaluated thus presenting a system which is a hybrid of the pure ranking system and paired comparison.

In many industrial situations the problem falls into one of two categories:

- (1) If a given process change is introduced will there be a noticeable improvement in quality justifying the costs of the modification.
- (2) If a cost reduction scheme is introduced, will it result in a noticeable deterioration in quality.

In both of these situations the word 'noticeable' implies a significant change in the distribution either by variance reduction or displacement of the mean. The former can result from tightening of a control range, the latter by alternation in level of process parameters. Appropriate experimental designs would employ a control which represents current methods and experimental factors using either tighter control range or alternative level of a parameter. In the case where the experiment assesses the effect of tolerance reduction, the level of the parameter for the control ingot is selected to be outside the proposed limits.

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If we assume that a quality attribute (e.g. appearance) of the conceptual population is normally distributed, with variation resulting from changes in many process factors, then strictly we need to know the magnitude of the mean and variance of the conceptual populations of both the current and proposed processes. This leads to the complex analysis previously considered. However, a designed experiment is carried out over a short time span and unusual measures are employed to maintain other variables as close as possible to their mid range positions, from which it follows that control material will tend to be close to mean and the variance will be much less than the conceptual population of current production. A similar situation exists between the mean experimental group and the anticipated mean of the conceptual population of the amended process. It is hypothesized that under these circumstances a significant change in quality occurs only if there is an "always noticeable difference" between the populations. The condition that the degree of scrutiny of the final product is much less than that in a paired comparison test is essential to this assumption.

The criterion of always noticeable difference can be evaluated using paired comparisons in which all control are compared with all experimental groups. Omitting within groups comparisons reduces the number of pairs evaluated for one data set from $n(n-1)/2$ to $n^2/4$.

The number of observations needed for a decision can be reduced further under the hypothesis that as a result of the control imposed, each group has approximately the same variance. Under this hypothesis an upper limit to the number of pairs requiring comparison can be generated, based on the probability that a specific degree of distribution overlap will be detected for a particular sample size.

A distinct advantage of the proposed method is that evaluation is aborted if it becomes evident that the hypothesis of an always noticeable difference is invalid. Thus prolonged testing occurs only when the result is likely to be useful industrially.

SUMMARY

Product acceptability is frequently determined by human response to sensory stimuli. Absence of industrial measuring devices prevents clear definition of standards and application of automatic control systems.

Development of a measuring system reflecting human response to visual appearance requires instrumental techniques to assess the density and distribution of the myriad of surface components influencing like-dislike decisions. These need correlating with material rated on a sensory scale. The complexity of this task makes industry reliant on assessment by inspectors who are subject to vigilance decrement and changing decision criteria.

Designed experiment to identify process parameters which adversely affect sensory related quality are hampered by absence of physical methods of measuring response. Discussion of evaluation methods suggests that paired comparison can be used, even when the number of samples evaluated is large, if the decision criteria is an "always noticeable difference."

ACKNOWLEDGEMENTS

The author is indebted to his wife, Sylvia, who first demonstrated that apparent anomalies in experimental data and differences in results between experiments were not inconsistent with the findings of psychological research. Special thanks are due to Dr. Douglas Mewhort, Department of Psychology, Queen's University, Kingston, for his helpful advice in design and analysis of experiments and stimulating the search for efficient methods of data analysis. The timely and enthusiastic support of Mr. Roger Fielding, Alcan Canada Products Ltd., Kingston, played a vital role in gaining acceptance of the use of new techniques in important experiments.

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DETERMINISTIC AND PROBABILISTIC FRACTURE MECHANICS

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ABSTRACT

"Deterministic" and "probabilistic" approaches for predicting crack growth in high performance aircraft are examined. Each approach is described in a simple conceptual manner for six basic elements of fracture mechanics. Concepts are reviewed and the potential of the "probabilistic" approach is discussed.

INTRODUCTION

Damage tolerance and durability requirements are now being imposed by the Air Force on current and future metallic airframes [1,2]¹. The effects of material and manufacturing flaws, such as, cracks, scratches and voids must be evaluated at three levels: (1) preliminary design, (2) final design and (3) service life tracking. Efficient and reliable analytical methods are needed to evaluate the behavior of flaws under expected service conditions. Structural performance, life and ownership costs depend on the flaw growth prediction methods used and fleet service life management activities.

A deterministic approach is currently used to predict level of damage (i.e., crack size) and life for aircraft structures [3,4]. The total crack length is predicted using an initial crack size and a linear accumulation of crack growth on a cycle-by-cycle basis. This method is inefficient and costly to implement because crack growth is predicted and accumulated for each load cycle in the load spectra. A more streamlined methodology is needed for predicting crack size for different materials, design concepts and load spectra and for tracking the cumulative damage of each aircraft in the fleet.

Methods have been proposed for simplifying crack growth analysis [5,6,7]. Progress has been made but further improvements are needed.

Current methods for predicting crack size are deterministically oriented although statistical and probabilistic principles are also used. It is called a "deterministic" approach because the variables in the analysis are considered as single values or constants with zero variance. A single prediction of crack size results for each set of values input.

Recently, considerable interest has been shown in structural reliability and probabilistic approaches in structural design [8]. A "probabilistic" approach considers the governing parameters as random variables. Each variable is considered as a distribution of values with a mean and variance. The feasibility of a probabilistic approach for predicting crack size in aircraft structures needs to be examined.

¹Numbers in brackets designate References at the end of paper.

The objective of this paper is to study the feasibility of a probabilistic approach for predicting cumulative crack growth in aircraft structures. This objective is satisfied as follows. The deterministic and probabilistic approaches are conceptually described and discussed for each of the following crack growth elements:

- o Initial Flaw Size
- o Fracture Toughness
- o Crack Length versus Time
- o Crack Growth Rate
- o Load Spectra
- o Crack Growth Accumulation.

The implementation of the probabilistic approach is discussed and the potential of this approach is assessed for near term applications.

PHILOSOPHICAL CONCEPTS

Deterministic and probabilistic approaches are characterized for six basic elements in Figures 1 and 2 respectively. Each element is conceptually described below. Many of the concepts are presented in an ideally simplistic form to aid understanding and comparisons. Basic definitions applicable to both approaches are given in the deterministic approach discussion. The term "approach", as used in this paper, refers only to the philosophical point of view reflected in the methodology and not the detailed procedures for predicting crack growth.

Deterministic Approach

The deterministic approach refers to methods for predicting level of damage (i.e., crack size) and life in which all input data are considered as discrete values. Thus, a single value prediction is obtained for a given data set.

Crack growth variables, such as, flaw size, fracture toughness, and crack growth rate are described by assumed probability density functions (PDF). These functions mathematically describe the distribution of possible values for each variable. Suitable functions are selected using available test results, prior experience or intuition. For crack growth analysis, one value is selected for each variable from its distribution of possible values. Selected values are considered as "worst-case" and they acknowledge that the distributions were estimated from finite sample sizes. For example, the 90th percentile estimated with 95% confidence. This idea applies to the items in Frame A through D in Figure 1.

Initial Flaw Size - An initial flaw size is required for critical areas of the structure to start the crack growth analysis. The distribution of initial flaw sizes is depicted in Figure 1, Frame A. One initial flaw size is selected from the distribution. Initial flaw sizes for damage tolerance are specified in MIL-A-83444 [1]. Large flaws grow to their critical length faster than smaller potential flaws when both are subject to the same stress history. This assumption is basic for the deterministic approach.

Fracture Toughness - This material property (K_C) measures the material's resistance to fracture. K_C is used to screen candidate materials and to predict the material performance of full-size structure using simple test results. Structural failure is predicted using K_C , applied stresses and probable flaw size. K_C is a random variable. For analysis purposes, one value of K_C is selected from the distribution of values to compute the critical crack length (Figure 1, Frame B).

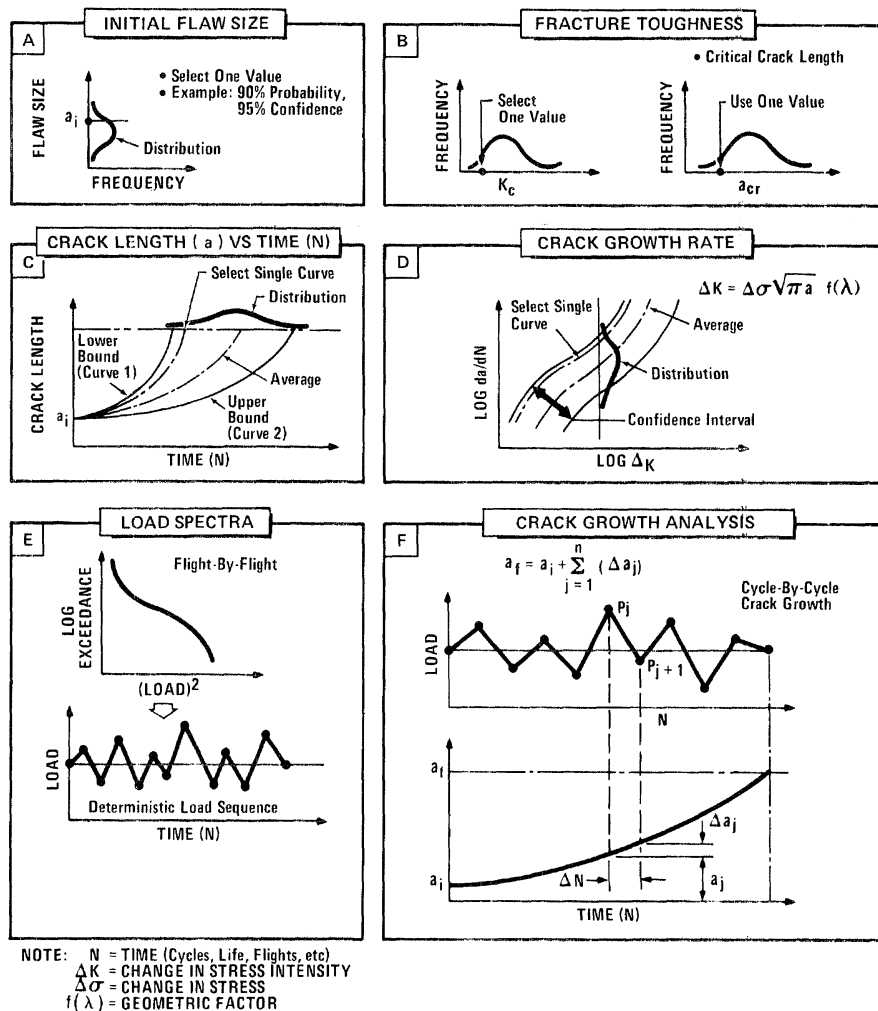


FIGURE 1 Elements Of The Deterministic Approach For Predicting Crack Growth

Crack Length versus Time - Crack growth data, such as crack length (a) versus time (N), are developed from constant amplitude tests. Tests are performed for a given material using replicate specimens. Results are used to evaluate crack growth rates. The crack growth performance of identical specimens with the same initial flaw size varies although specimens are subjected to comparable constant amplitude testing (Figure 1, Frame C). For example, curve 1 shows faster crack growth than curve 2 in Figure 1, Frame C. For analysis, only one "a" versus "N" curve is selected for a specified probability and confidence level.

Crack Growth Rate - Incremental crack growth is predicted for different materials and loading situations using this information. The crack growth rate, da/dN, is derived from a (crack size) versus N (time) test results. Log-log plots of da/dN versus ΔK are depicted in Figure 1, Frame D. The plotted data is bounded by a confidence interval. One da/dN versus ΔK curve is selected for a given probability and confidence level for analysis purposes.

Load Spectra - Loads are defined using a load-exceedance curve. A load history, with a specified load sequence, is needed to perform the crack growth accumulation analysis (Figure 1, Frame E). Current practice is to simulate the overall life on a flight-by-flight basis. Each flight in the load spectra includes a series of cycles that combine the deterministic and probabilistic events describing the type of mission. Deterministic events include takeoff and landing and certain maneuvers (such as cruise, climb, TFR, etc.) during each flight. Events such as gusts or rough field taxiing occur periodically. The number of times these events occur can be estimated but their position in the load sequence is determined in a probabilistic manner. An infinite number of load sets with different load sequences are possible to represent the service usage of all aircraft in the fleet. However, a specific load history simulation, that includes a specific sequence of loads, is used in the deterministic crack growth accumulation analysis. The aircraft usage severity is a random variable but the effect on the predicted crack growth accumulation is considered in a deterministic manner.

The deterministic load history (with a specific sequence of loads) is transformed into a stress history for each critical area of the airframe. This is accomplished by determining the relationship between the load history and the stress response of the structure in the critical areas.

Crack Growth Accumulation - The crack growth is accumulated by adding to the current crack size a crack growth increment, which reflects the effects of the next load cycle (Figure 1, Frame F). Crack growth accumulation is computed using:

$$a_f = a_i + \sum_{j=1}^n (\Delta a_j) \quad (1)$$

where, a_i = initial flaw size

Δa_j = crack growth increment associated with the j th load cycle.

Load interaction models account for load sequence effects on crack growth increments [9-11]. Thus, the predicted crack size is accumulated on a cycle-by-cycle basis assuming that crack growth is a deterministic process.

Probabilistic Approach

The "probabilistic" approach refers to methods for predicting the distribution of crack sizes (or damage) and structural life by considering the governing parameters of crack growth as random variables. Variables, such as flaw size, fracture toughness, crack growth rates, loads and environment are considered as statistical quantities. Values for these variables are treated as statistical distributions with a mean value and variance. Results are presented in terms of probability of equaling or exceeding a specified value for a given data set. The goal is to predict the distribution of damage and life in a statistical format so that the probability of reaching specified limits can be determined.

Initial Flaw Size - An initial flaw size distribution describes the population of potential initial flaws in the structure (Figure 2, Frame A). Whereas the "deterministic" approach considers a single "worst case" flaw size for analysis, the "probabilistic" approach treats initial flaw sizes as random variables.

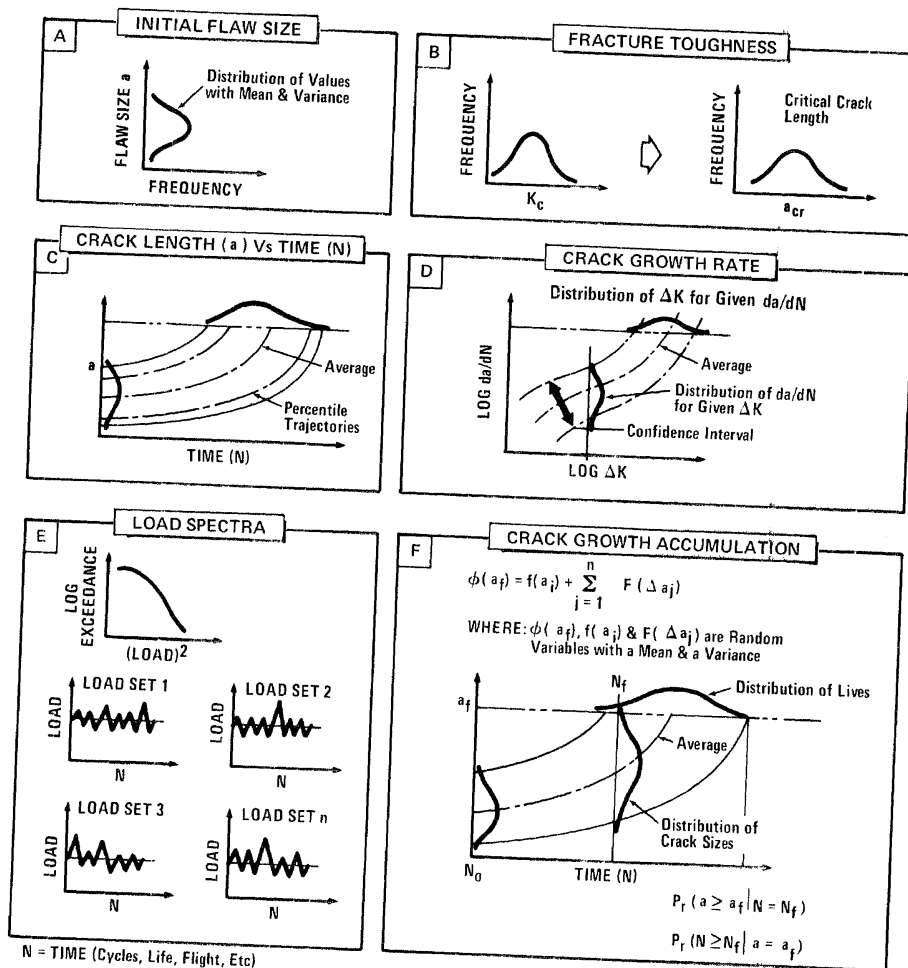


FIGURE 2 Elements Of Crack Growth In Conceptual Probabilistic Form

Fracture Toughness - K_{IC} values and critical crack lengths (a_{CR}) for a given material and stress level are treated as random variables (Figure 2, Frame B).

Crack Length Versus Time - The distribution of flaw sizes are considered as a function of time. The time to reach a specified flaw size is treated as a random variable (Figure 2, Frame C).

Crack Growth Rate - da/dN and ΔK (delta stress intensity) are treated as random variables (Figure 2, Frame D). Crack growth rate is a statistical distribution for a given ΔK and vice versa.

Load Spectra - The "deterministic" approach uses a specific load set and load sequence. Using the "probabilistic" approach, multiple load sets can be derived from the load-exceedance curve (Figure 2, Frame E). Load spectra are considered as statistical quantities.

Crack Growth Accumulation - The current crack size is considered a random variable (Figure 2, Frame F). Symbolically, the crack size can be expressed as:

$$\varphi(a_f) = f(a_i) + \sum_{j=1}^n F(\Delta a_j) \quad (2)$$

where: $\varphi(a_f)$ = distribution of current crack size

$f(a_i)$ = distribution of initial flaw size

$F(\Delta a_j)$ = distribution of crack growth increment
which depends upon such things as the
crack growth rate, load history and
environment.

IMPLEMENTATION OF PROBABILISTIC APPROACH

The purpose of this section is to discuss, in general terms, the implementation of the probabilistic approach for predicting crack growth. The probabilistic approach for predicting crack growth is conceptually described in Figure 2 for six basic elements. These concepts are described in a philosophical manner without regard to their implementation in a detailed crack growth analysis procedure.

The distribution of crack sizes after a given service time, or equivalently the distribution of service time to reach a given crack size, is the goal of the methodology regardless of how many of the basic elements are allowed to be random variables (Figure 2, Frame F). The problem is to derive these distributions for selected aircraft control points using the expected service conditions (loads and environment) and predicted structural response. Once these distributions have been defined, probabilistic principles can be used to predict:

- o the probability that the cumulative crack size is equal to or greater than a specified crack size at a given time period, i.e.,

$$Pr(a \geq a_f | N = N_f) \quad (3)$$

- o the probability that the life is equal to or greater than a specified value for a given crack size, i.e.,

$$Pr(N \geq N_f | a = a_f) \quad (4)$$

Two possible methods for deriving the needed distributions are:

- (1) Analytical Derivation [12] and (2) Monte Carlo simulation [13].

Analytical Derivation [12]

Theoretically, the crack length distribution can be analytically derived as a function of time. A simple example illustrates the essential features of the analytical derivation without introducing the mathematical details (Figure 3). There are two basic problems: (1) characterize the initial crack length distribution and (2) determine the crack growth relationship as a function of time. First, the initial crack length is assumed to be a random variable. The functional form of the distribution of initial crack lengths is assumed (Normal, Weibull, Log-Normal, etc.). Parameters for the distribution are estimated from available data.

A mathematical expression, $F(N)$, is needed which describes the growth of an arbitrary crack as a function of time. $F(N)$ is substituted into the initial crack size distribution to obtain the desired transformed distribution of crack sizes. The distribution of times to reach a given crack size is determined in a similar manner. $F(N)$ depends upon the crack growth process and the derived equation yields a single value of $F(N)$ for a given N value. Thus, the transformed distribution is obtained using a deterministic equation.

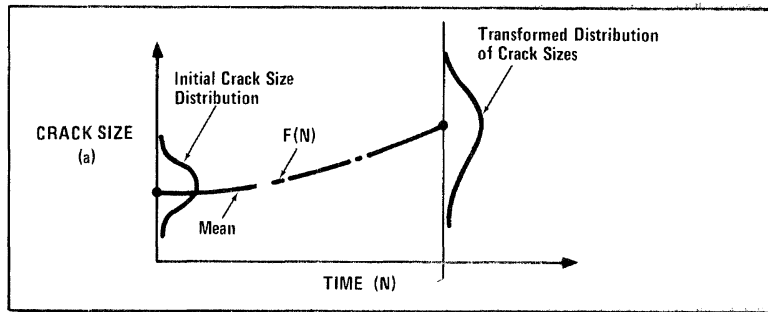


FIGURE 3 Transformation Of Initial Crack Size Distribution

Monte Carlo Simulation [13]

A distribution of values (PDF) is defined for each significant random variable in the crack growth process. One value of each variable is randomly drawn from applicable populations. These values are substituted into a model or equation which characterizes the crack growth process. The result is a single value for a crack size at a given time or the time to reach a given crack size. One prediction is obtained for each data set. New data sets are drawn and the above calculations are repeated to establish the distributions needed to implement the probabilistic approach (Figure 4).

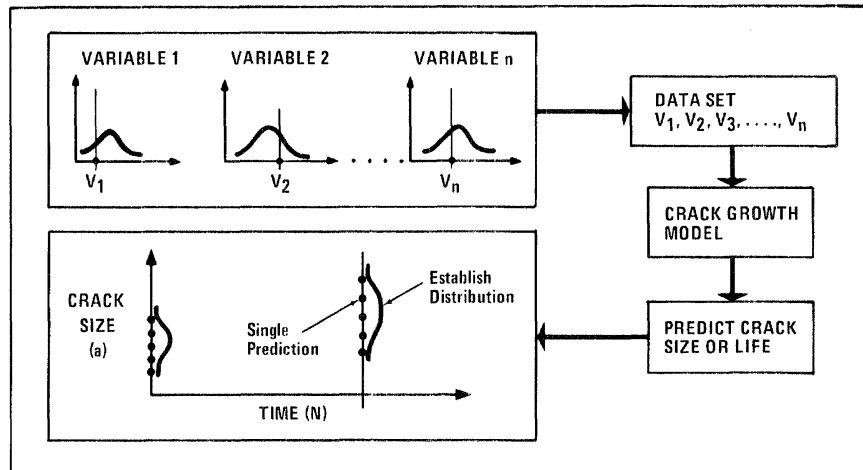


FIGURE 4 Monte Carlo Simulation To Define Distributions

Problems

Several problems must be considered to implement the two methods discussed. This includes such items as:

- o Error and uncertainty
- o Lack of data to support analyses
- o Joint distributions
- o Proven model for crack growth process
- o Significant crack growth variables and their inter-relationships
- o How to apply simple data to complex structure

Further discussion of these problems is beyond the scope of this paper.

POTENTIAL OF PROBABILISTIC APPROACH

Is it feasible to implement a "probabilistic" approach for evaluating crack growth and also satisfy the Air Force's damage tolerance [1] and durability [2] requirements? If so, this approach should be responsive to the designer's needs at the preliminary and final design levels. It should provide design data, such as, allowable stress levels for different materials, design concepts, load spectra, and environment. The specified design allowables must satisfy the damage tolerance and durability requirements. Reliable results are needed quickly to meet schedule and cost requirements. Also, procedures should be reliable and efficient for evaluating the cumulative damage for fleet members under service conditions and for evaluating fleet maintenance and repair requirements.

Using the above criteria, the "probabilistic" approach for predicting crack growth, in which all parameters in the crack growth process are treated as random variables, is not feasible for near future aircraft applications. Presently, an approach that includes both deterministic and probabilistic features is the most promising. However, several issues must be resolved before the combined "deterministic/probabilistic" approach envisioned can be implemented with confidence. First, a better understanding of the crack growth process is needed for different materials, design concepts and operating conditions. Second, the significant crack growth variables and their inter-relationships must be better defined so that emphasis can be placed on the proper variables and their statistical characterization. Third, better deterministic models are needed to describe the crack growth process. Such models are essential for implementing the combined "deterministic/probabilistic" approach for predicting crack growth.

Monte Carlo simulations would be time consuming for implementing the probabilistic approach. For this reason it would be too inefficient for the needs of preliminary and final design and for tracking the cumulative damage of fleet members.

Mathematical transformations are promising for implementing the probabilistic approach. However, improved models and statistical characterization of the crack growth process are needed.

CONCLUSIONS

A classical "probabilistic" approach, in which all variables and the crack growth process are considered random, is not practical in terms of the present state-of-the-art. For near future applications, the deterministic approach, including the use of statistical and probabilistic principles, is the most promising for predicting crack growth in aircraft structures. The combined "deterministic/probabilistic" approach is promising but further development and understanding of the crack growth process are needed to implement it. It should be recognized that the deterministic approach can be generalized into an increasingly more probabilistic approach by regarding one or more of the crack growth parameters as random variables.

The most efficient way to streamline the existing crack growth methodology with the present understanding, is through statistical characterizations of the load spectra and structural response. A better understanding of the mechanisms of crack growth is needed. This involves defining the significant crack growth variables and their relationships.

Improved load-interaction models should be developed to replace the inefficient cycle-by-cycle models [9,10,11]. New models should place greater emphasis on the use of statistical and probabilistic principles for characterizing crack growth and the load spectra. Statistical and probabilistic principles are valuable tools for evaluating the effects of variability. These tools should be fully exploited to further the crack growth analysis state-of-the-art.

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QUALITY ASSURANCE OF METAL IN CAN MANUFACTURING

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INTRODUCTION

The manufacture of two-piece beer and beverage cans by the draw-and-iron method has been commercially significant for only a little more than a decade. Today, it is a major manufacturing process involving some two dozen companies at nearly one hundred locations producing annually about 30 billion two-piece cans worth over 2.5 billion dollars.

Coors Container Company was an early entrant in two-piece can manufacture, and was a significant contributor to its rapid expansion. While such cans are made today in both steel and aluminum, Coors has worked commercially only with aluminum, and today has a yearly plant capacity of over 3.5 billion cans at its single Golden, Colorado, location. Coors' first two-piece can line for 11-ounce cans was designed to run at a speed of 1000 cans per minute. That same line now manufactures cans at over 1800 per minute, and the newest line is designed to reach speeds as high as 3000 cans per minute.

During the same decade of progress in speed of manufacture, the price of aluminum stock for making cans has escalated from less than 30 cents per pound to more than 70 cents per pound, and coated metal for end making has risen from 45 cents per pound to nearly one dollar per pound. It is not surprising then that an effective quality system is essential to control and improve the costly material that feeds this high volume, sophisticated process.

THE QUALITY SYSTEM

The metallurgical quality system at Coors is dependent on two basic requirements: first, a thorough understanding, not only of the can making process, but also the fabricating process of the sheet; second, a close liaison with our supplier's technical, sales, and quality personnel for rapid response to problems.

A quick examination of the quality variables and attributes as they relate to mill fabricating operations will reveal the importance of those requirements.

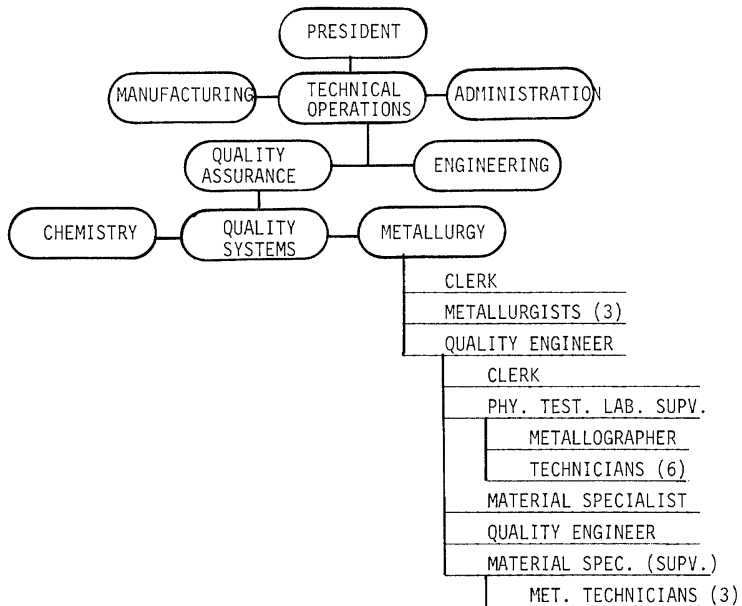
TABLE I.

<u>Mill Operation</u>	<u>Can Stock Defect/Attribute</u>
1. Melting	1. Composition, cleanliness, inclusions
2. Casting	2. Surface oxide, grain size, insoluble precipitate size
3. Scalping	3. Surface quality, slivers, tears, rolled-in-oxides
4. Preheating	4. Homogeneity, solid state transformations, formability, non-galling
5. Hot rolling	5. Gauge uniformity, edge cracking, earing, oxide pick-up, shape
6. Annealing	6. Grain size, earing, oxide surface, properties, scratches
7. Cold rolling	7. Final gauge and variation, scratches, shape, flatness, rolled-in-dirt, oxide, etc.
8. Slitting/inspecting	8. Width, edge burrs, flatness, even coil wind, dirt, oil, edge cracks, gauge
9. Pack/ship	9. Correct weight/footage, clean moisture free package, no shipping damage.

One look at the above list should make several things apparent. No amount of wishing at the can plant will make off-specification material work. Corrective action must be taken by the supplier at his mill. Rapid and accurate feedback from the user is the only practical way to achieve that result. This is extremely important when one adds the fact that in the pipeline at any given time is a supply of material worth several million dollars.

How do we assure rapid and accurate feedback for corrective action? With people! Figure 1 is a diagram of the organization at Coors Container Company, detailing the Metallurgical and Physical Testing Department.

Figure 1. Coors Container Company Organization (partial)



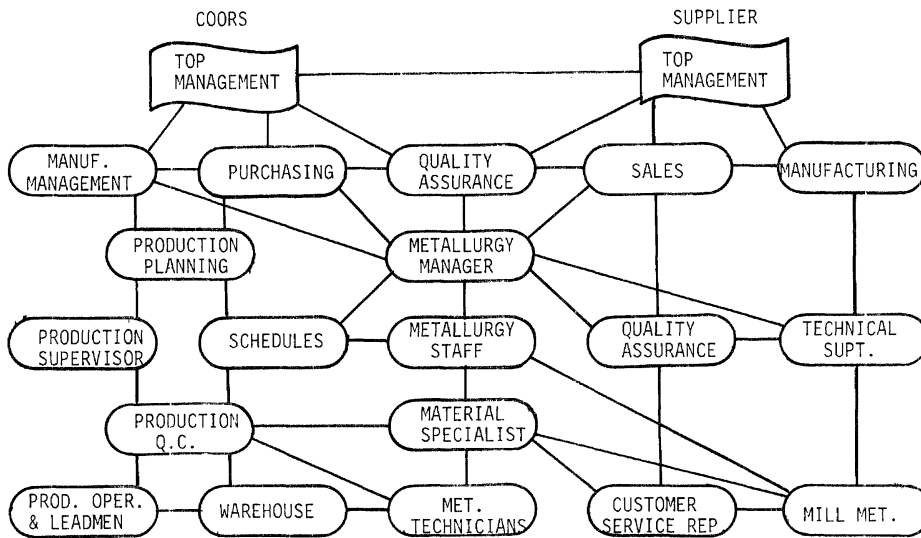
The Metallurgy Department has primary responsibility for metal in the following areas.

- I. Quality
 - A. Specifications
 - B. Vendor capability audits
 - C. Incoming inspection
 - D. Material/process audits
 - E. Material traceability
 - F. Vendor source audits
 - G. Problem solving
 - H. Material disposition
- II. Research and Development
 - A. Qualification
 - 1. New suppliers, locations
 - 2. New practices, processes
 - 3. New alloys
 - B. Evaluation
 - 1. New forming concepts
 - 2. Minor practice or process changes
 - 3. Material processes
 - C. Technical liaison
 - D. Supply and Demand (metal)
- III. Physical Testing
 - A. Metals and coated metals
 - B. Division support
 - C. Corporate support

THE TEAM CONCEPT

How does the organization in Figure 1 accomplish the above mission, including the rapid feedback to implement corrective action on defective materials? It does so as a member of a team, or rather of several teams, which in concept extends throughout the Coors organization and into the organization of each major material supplier. A typical team member interface is shown in Figure 2.

Figure 2. Metal Quality Team Interfaces



The above matrix is an interface, not a hierarchy, and emphasizes membership on a team for a specific function. A team could have as few as two members, and as many as needed. Three or four is most common. The membership of a team varies with the nature of the task, and a team has no official life beyond the life of the task.

For example, in incoming inspection of metal, the team begins with the material specialist and warehouse personnel who identify a rail car lot and sample size, and arrange to stage the sample to production lines. The team enlarges to include production operators, leadmen and metallurgical technicians only if the sample creates a problem. The team will identify the nature of the problem and isolate the shipment from which the sample was taken until the extent of the problem is determined. If the problem is not routine and requires metallurgical analysis, the team is joined by one or more of the staff metallurgists, who are regularly occupied by important, but less urgent R & D.

If the problem is then recognized as going beyond just a coil or two, the supplier's sales representative is contacted, and possibly direct contact is made with mill metallurgists in the supplier's quality or manufacturing organization to begin the correlation of material performance and process data. The enlarging circle of team members could encompass the entire interface shown, and it has happened. The objective, however, is always to make disposition when the circle is the smallest. The emphasis in all problem solving is the solution and permanent corrective action, never the blame. This attitude has permitted us to develop mutual trust and share even proprietary company information, which we guard carefully.

THE TECHNICAL PARTNERSHIP

This close relationship has become what we call a "technical partnership" and is the sought-after relationship with all of our major suppliers. It is based on the simple recognition that the ideal quality position for both supplier and user is that which promotes the lowest cost to both. With this common objective, each is receptive to the efforts of the other to reduce cost or improve quality. In an industry

where material cost can represent 60% or more of the finished product cost, your supplier's costs should concern you as much as your own.

An example of mutual benefit derived from the technical partnership is a situation in which one supplier approached us to request our use of a modified alloy for tab stock at a time when primary metal was in short supply and they needed to use more scrap. However, the average manganese level from using scrap would be higher than the tab alloy composition allowed, and would raise the strength level, with some loss of formability. The higher strength could be compensated by reducing the amount of magnesium, which offered some savings in alloy costs since the price of magnesium was three times that of aluminum at the time.

Coors accepted the challenge, evaluated the modified alloy, which resulted in a further adjustment in composition and improvement in properties, and adopted it not only for our tab stock, but for our end stock as well. Many tab stock users still refuse to switch, while Coors enjoys annual savings exceeding \$200,000, and know we have added to the latitude of our supplier's operation and enhanced the recycling of scrap into useful products.

On another occasion, the same vendor came to Coors with a problem in which their remelt furnaces were being damaged as a result of the ignition of oil residues on recycled scrap from the can plant, and smoke emissions from the same source were unacceptable to their local EPA. Very serious, indeed! While they continued to evaluate furnace modifications to handle the oil residues, Coors looked at our own system to see if the residues, then running about 4%, could be reduced. An engineering project was established and implemented at a cost exceeding \$100,000. In the meantime, the supplier imposed penalties in its scrap buy-back policy that created a significant incentive, with different penalties at 4% and 2% residual, and no penalty below 1%.

By the time the penalties were in effect, Coors was below 2%, and three months later were in the non-penalty level just below 1%. We continued our engineering plan and today ship scrap with about 0.5% oil residue, enjoying over \$300,000 in reduced cost and taking pride in not contributing to the air pollution in southern Indiana and other places around the country.

A third example of benefits of technical cooperation resulted from studies at Coors to correlate the tendency of certain lots of aluminum can stock to gall and build-up on tooling, creating a scratched can wall that was less shiny and was subject to splits in the flange. Metallographic examination of the metallurgical structure was related first to the galling characteristic and then to composition. Working closely with our suppliers, the correlation was verified, and the standard composition of can stock now treats a former "impurity" as a necessary constituent with a minimum amount required.

In still other programs we have significantly improved can stock quality, reduced energy usage, improved metal recovery on remelt, evaluated and qualified cheaper alloys and new fabricating practices, all resulting in some incremental savings in fuel, metal weight in cans and better efficiency and higher profits for ourselves and our suppliers than might otherwise have been possible.

The quality assurance of metals in can making at Coors contains most of the elements of quality systems everywhere, but its success is the result of highly motivated people participating, communicating and innovating through teamwork.

IMPROVING AUDIT EFFECTIVENESS

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INTRODUCTION

During the past five years our audit teams have performed over 150 audits. These audits evaluated:

- The Construction Phase QA Program
- The Operational QA Program
- Compliance To Technical Specifications
- The Qualification And Training of Personnel
- The Corrective Action Cycle
- The Emergency Plan
- The Security Plan
- Non-Radiological Environmental Monitoring

Our analysis of these audits has identified five stages in the audit cycle where improvements can be made that not only make for a more efficient program but one that will instill more confidence in the results and obtain more meaningful corrective action. Most of these improvements can be instituted with a minimum of effort and will assure a more professional approach to auditing.

ESTABLISHING THE PROGRAM

There are four steps that should be taken prior to starting any audit program to assure that the program has a firm foundation.

INDOCTRINATION - Senior management as well as management of the organizations implementing the programs to be audited must know the objectives and limitations of the audit program. It is extremely important that everyone in management realizes that an audit, no matter how well conducted, is no substitute for an effective QA Program (or any other program subject to audit). An audit can only measure and report on the effectiveness of a program at a particular point in time. It can not take the place of the program nor can it be used as an alibi for the lack of a program.

ORGANIZATION - Because many different organizational elements implement the programs that are subject to audit, the responsibility for audits is assigned to our corporate QA&R Department with an overview of the program residing in the Nuclear Facility Safety Committee (NFSC). Furthermore, our audit group is totally independent of the line QA organizations responsible for developing departmental programs and procedures subject to our audit. If there were no corporate QA&R Department, our audit group could, report to the NFSC to assure that it had the organizational independence necessary for an effective audit program. This same independence should be provided in any company in order to have a meaningful audit program.

PRESENTATIONS - Senior management or the NFSC should be given periodic reviews of the status of the audit program to assure that the direction of the program continues to meet corporate policy and that organizations responsible for taking corrective action do so in a timely manner. The mere fact that organizations know that the status of corrective actions will be reviewed by higher level management has been a definite help in obtaining timely action to remedy deficiencies.

STAFFING - The audit team leaders are the key members of the audit group. They should meet ANSI requirements, as a minimum, and must be capable of training personnel to act as audit team members. There is no need to maintain a large audit staff, for the most effective utilization of personnel is obtained by having only the audit team leaders as permanent members of the audit group. Team members for individual audits can be selected from other departments within the company (provided that they do not have any responsibility for the program being audited).

PRE-AUDIT ACTIVITIES

Prior to starting an audit, there are four steps that, if taken, can reduce the amount of time spent on an audit and/or improve the chances of finding non-compliances to regulatory requirements.

PROCEDURE REVIEW - Most audit teams review those procedures pertaining to the subject undergoing an audit just prior or at the start of an actual audit. This is too late. The best time to review procedures is prior to their issue when they are circulated for comment by affected departments. If the comments of the audit group are obtained/resolved at this stage, much wasted effort in training personnel on the procedure and implementing known deficient procedures can be avoided. Furthermore, if there is an appreciable time lag between the issuance of the procedure and a company audit to evaluate its implementation, this pre-release review may prevent the NRC from faulting it should they audit during this period.

During any review of procedures, it is very important that procedures that cross departmental lines are coordinated with and agreed to by all affected departments. If they are not, the department that developed the procedure may not obtain the cooperation of the other departments that are necessary in implementing the procedure, or worse yet, these other departments might not even know of the procedures existence. This can be very easily ascertained during the pre-issuance review performed by the audit group.

A final check that should be performed during this pre-issuance review of procedures is to assure that all regulatory requirements have an implementing document that meets the full intent of the regulatory requirement. This is best accomplished by developing a matrix showing the relationship between the company's implementing procedures and regulatory requirements. Once this matrix is developed any gaps between requirements and procedures become quite obvious. Furthermore, if instead of gaps you have too many overlapping procedures, action can be taken to consolidate or eliminate them.

FLOW CHARTS - Prior to performing an audit most team leaders prepare itemized check lists for evaluating the audit subject. A valuable supplement to an audit check list is a flow chart, especially for subjects, such as maintenance, procurement, etc. where the paperwork flow and decision process cross departmental lines. These flow charts are especially valuable in determining the "effectiveness" of a program and save auditors considerable time because key decision points in a process are obvious and by evaluating these key points a speedier assessment of the program is possible.

SYSTEM TYPE AUDITS - Instead of auditing a single criteria of 10CFR50, Appendix B (e.g. Procurement Document Control) or a particular paragraph of the Technical Specification, we have found it much more effective and less time consuming to audit complete systems. Our procurement cycle audit covers applicable portions of 13 of Appendix B's 18 criteria so that we can evaluate the effectiveness of the procurement system in-toto rather than on a piecemeal basis. This not only saves the audit team's time but that of all personnel involved in the procurement cycle. It also increases our chance of detecting non-adherence to regulatory and company requirements and enables us to present one composite picture of the systems effectiveness to senior management.

ANALYSIS - Before starting an audit, team leaders review prior results for open items, reported corrective actions, or trend items that should be evaluated during an upcoming audit. These are not the only items that should be added to the audit's agenda. Previous NRC inspection reports, minutes of safety committee meetings, industry/technical society meeting reports, trade journals, etc. all contain information that should be evaluated for application on your audits. The more information that you use to guide your audits, the more effective your program becomes.

CONDUCTING THE AUDIT

There are four measures that can be taken during the conduct of the audit that can improve its effectiveness.

TEAM SELECTION - Members of the audit team should have a thorough knowledge of the subject being audited and no direct responsibility for it. There is usually no problem in finding personnel to meet these criteria. In conducting audits of our QA program we have found it beneficial to use as team members personnel from the corporate QA staff. They developed the QA program and trained the operating and support personnel in its use but have no direct responsibility for the operation of the program. Because of this they are ideally suited to evaluate the implementation of "their" procedures. Furthermore, by evaluating the implementation of the procedures they prepared, valuable insight is gained that is useful in revising procedures that have become outdated or inefficient. Their presence is also helpful when reviewing deficiencies in implementing procedures at exit interviews.

IDENTIFYING AUDITED MATERIAL - It is important to have a simple procedure for identification. Identifying procedures reviewed during an audit so that they are not reviewed again on subsequent audits (provided they haven't been revised) is relatively easy to do. However, identifying records that have been reviewed can be much more difficult. Limiting the scope of an audit to certain time periods is one method of preventing the same record from being reviewed more than once. Signing the record or stamping it is another.

VERIFYING ACTIVITIES - The key activity on any audit is the verification that procedures are properly implemented. Aside from problems in scheduling to assure that the audit is performed when there is activity (e.g. as during an emergency drill), there are problems in determining which jobs, which personnel, which shift should be reviewed once the audit has started. Merely reviewing records of completed jobs does not give any real indication of whether or not governing procedures were followed. A few general rules can be established that will increase the chances of detecting non-compliance to procedures,

Namely:

- (1) Audit on-going jobs only. This enables you to verify that the material, tools and gages, work instructions, personnel qualifications are acceptable.
- (2) When auditing on-going jobs question the worker performing the activity. It doesn't do any good to just question his supervisor, for the worker is doing the job and if the worker either doesn't know what procedures to follow, or takes short cuts - there is a lack of control that must be corrected.
- (3) Check activity on second and third shifts. Make sure that information necessary to continue jobs properly is passed during the change of shifts.
- (4) When evaluating the procurement cycle, audit approved vendors to check on vendor approval procedures and visit vendors when surveillance inspection is being conducted to verify that the surveillance inspection plan is being followed.

CONCURRENCE ON NON-COMPLIANCES - When a non-compliance to company procedures or regulatory requirements is detected, a management representative from the audited activity should be informed as soon as practical, preferably by bringing him to the area where it was found and reviewing the non-compliance with him. Ideally the audit reporting forms should provide for his signature indicating that he has seen the non-compliance. This compels firm to start the corrective action process and eliminates unnecessary "hassling" during the exit interview.

POST-AUDIT ACTIVITIES

After completion of the audit, four steps should be taken to assist in the analysis of the results and implementation of corrective action.

INDEXING - One of the major problems encountered in analyzing audit results is to determine if the trend shown by the results is getting better, or worse, or remaining essentially the same. Because of the different programs involved in auditing (QA, Training, Security, etc.) any analysis of results should be on a program basis. Because different audits may vary greatly in magnitude (i.e. in the number of inspection points observed) the "P" chart is the best one for analyzing the results. The sample size, n, associated with this chart can either be the number of checklist points evaluated or the number of records reviewed (especially appropriate for the corrective action audit).

SEVERITY LEVELS - Not all non-compliances are equally severe; even the NRC has recognized this. Therefore, when reporting your non-compliances, the method used by the NRC of having three levels of severity can be used. This does not make the indexing problem unmanageable as scaling factors can be used in conjunction with control charts or separate control charts can be established for the different levels of severity.

FOLLOW-UP SYSTEMS - In order to assure that timely corrective action is taken on non-compliances found during audits, an efficient follow-up system must be maintained by the audit team and the organization that was audited. Both groups need follow-up systems, the audited organization to assure action by them, the audit group to assure completion and verification of the corrective action. To assure effective follow-up our audit group publishes a monthly status on corrective actions and distributes copies to affected organizations. It is planned that our audit findings will become part of the company's Licensing and Regulatory Status Report which lists the status of all commitments to the various regulatory agencies.

FEEDBACK - Audit results are normally transmitted to the audited organization and senior management. Two additional organizations should be included on these reports - the training group and the technical group(s) responsible for generating procedures pertaining to the audit subject. The training group may decide, based on the audit results, to initiate or update training programs to indoctrinate or motivate personnel on company procedures. The technical group responsible for procedures may decide, based on audit results, to revise existing procedures or initiate new ones in order to provide the control necessary to prevent future occurrences of non-compliances cited in the audit report.

FUTURE PLANS

The suggestions discussed above are ones we have reviewed and found helpful to our audit program. We are presently evaluating several items that we feel would be extremely useful to our audit program.

DATA BANK - All of the data generated by the Tech.Spec., Corrective Action, and QA Programs is presently prepared, analyzed, filed manually. If this data were entered on optically scannable mark sense records and cards both the generating station and the audit group could reap tremendous benefits. Continuously updated analyses could be performed, data retrieval would be very rapid, and the audit group could develop programs to selectively scan data and put key jobs on hold for audit.

COST INFORMATION - There is a real need to develop accurate cost information on your audit program. Not just the cost of your audit group but of the effort expended by the organizations undergoing audit. Our Cost Accounting System enables us to recapture the cost of our auditors on each discrete audit program but does not yet permit us to obtain cost information for organizations that we audit. This cost information, together with the previously mentioned data bank, will enable us to restructure our audit program for maximum cost effectiveness.

CONCLUSION

The methods presented for improving an audit program represent the results of five year's experience. Hopefully they can benefit your program as well as ours. As you gain experience and find better ways to run your audit program, share your knowledge as it benefits both utility and consumer.

LSC 345:10:549

IS YOUR QA ORGANIZATION AIMED AT THE RIGHT STAR?

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INTRODUCTION

A functional staff management review provides the Quality Manager or a sub-unit of the Quality organization management with a peer evaluation of the overall effectiveness (doing the right things well) versus just efficiency (doing potentially the wrong thing without waste) of the organization.

The top manager of the organization being reviewed establishes a two- to four-day agenda designed to cover the quality subsystems described later. Approximately 75% of the time is structured and the balance open to last-minute items of review-team interest.

ISSUES

Which Star In The Constellation?

The basis for the entire review is the organization's mission (hopefully not impossible) which should be stated in a management-by-objectives format. The description of the mission should define continuing responsibilities and then special one-year and three-year objectives.

A useful way to look at the desired direction is to consider what things are designed to control change and then what objectives are meant to create change.

If the review team is not familiar with the product menu, then you must provide them with a basic understanding of the products' purpose, function, and technologies as a necessary launching pad for their review.

Strategies To Hook Your Wagon To A Star

The details of a total quality system are covered much more eloquently by other papers at this conference and by quality control handbooks, such as the one edited by J. M. Juran, which provide checklists in excruciating detail. Since this review is effectiveness oriented, the best approach to understanding the organization strategy is to look at the operating philosophy in a minimum of the following quality system components:

1. The procurement subsystem, or how does the supplier know what you want and how do you make sure that he gives it to you?
2. The in-process subsystem, or does the operator have the tooling, measurement equipment, training, and data collection capability necessary to produce a quality product?
3. The testing subsystem, or how well can you predict on a short-term and long-term basis what the customer will experience with your product?
4. The new product introduction subsystem, or will the three subsystems previously mentioned have the proper resources at the right time to meet your new product schedule and cost commitments?
5. The communication subsystem, or are there more feedback loops than in a modern, multi-level highway interchange so that the testers know what the customer thinks; the process people know what the testers think; the purchasing and suppliers know what the process experience is; and the new product planners understand how to better implement the next new product.

Another indicator of the strategy direction is the type of people within the Quality organization. An analysis for the review team of the organization's personnel by skills and/or job codes on one axis and degrees on the other axis gives one view of people placement. Another perspective is a second matrix showing product assignment on one axis versus prevention, detection, and failure (or resultant) manpower allocation on the second axis. Another interesting view is shown by comparing skill level or product assignment by time in the job.

BUSINESS

Product Planning, Or Is Your Astrologer Up-To-Date?

A small amount of preventive effort can be an indication that the organization is sacrificing tomorrow for today's crisis. TNT (The Next Thing) can truly explode next month or next year without adequate planning for new technologies or required new measurement techniques.

The area of product planning lends itself to full documentation, which in turn allows rapid review. This review should concentrate on coverage of the entire product menu, the currency of the plan, the necessary detail, and the practicality of implementation.

Quality Costs, Or Can You Afford To Get Off The Ground?

Although it is tough in today's complex accounting systems to segregate the elements of quality cost, the effort can be educational and revealing. The segments of quality cost typically are:

1. Prevention Costs - The costs associated with planning, early analysis, information collection technology, and initial new product implementation.
2. Appraisal Costs - The dollars spent on inspection or testing, regardless of whether it's done by an inspector or an operator, and the cost of the equipment required to do the inspection or testing.
3. Resultant (sometimes called "failure") Costs - All the costs which would not occur if the total quality system produced no defects. These include reclamation activity, scrap, rework, field replacement, and customer complaint handling.

Distribution of the quality costs among the above categories will depend on where the product is in the development cycle, the complexity of the product and its similarity to previous products, the amount of new technologies used, and the philosophy of inspection.

Product Liability Control

The suggested approach here is to define a short, mock product-liability complaint to see how well the organization can respond to any consumer-product-safety reporting requirements, can track the product to the producing process, and can produce the key documents needed to verify commercially acceptable quality practices.

WITNESS

Interfaces (If Not Love, At Least Respect)

This phase of the review can be the most revealing and can guide the team in how to spend the 25% of unstructured time looking at questionable areas. The concept is to interview key management and/or working professionals in each of the areas which Quality services. Each area should be asked for an overview of the Quality organization's effectiveness. In addition, specific probing should include the following areas of interest.

1. Purchasing
 - Are standards and specifications clear?
 - Is gauging compatible?
 - Are peak workloads adequately planned?
 - Is rapid and understandable feedback provided for in-process defects?
 - Does the supplier rating system do its job?

2. Manufacturing

- Are in-process quality goals defined?
- Are rapid measurement methods in place?
- Are critical process capabilities completed?
- Is there fast, understandable, problem feedback?
- Is there timely disposition of scrap and rework?

3. Engineering

- Is process capability information available as required?
- Is an adequate design review in place to verify a measurement capability?
- Are problems fed back rapidly in Pareto order?
- Are special studies performed by Quality when requested?

4. Sales (Marketing) And, If Applicable, Field Repair

- Is Quality responsive to special requests such as customer tours?
- Is there a timely, understandable, field problem feedback system?
- Does Quality understand the customer environment?
- Is Quality responsive to emergency field needs?
- Does any specific product's quality significantly hurt the sales effort?

Professional Vitality

A clue to troubles to come is a stagnant organization, not interested in renewing itself.

Indicators of the vitality of the Quality organization include:

- Outside activities in professional societies and technical paper presentation.
- The amount of training undertaken - on the job, voluntary vocational, self-development, and university.
- The amount of job rotation.
- The number of patents and awards received.
- The number of significant innovations implemented within and/or by the Quality organization within the last year.

Delegated Activities

Under some Quality philosophies, inspection, measurement development, supplier interface, and similar activities can be delegated to organizations outside of the direct Quality one. The review team must carefully examine the two-way communications with the organizations to whom the activities are delegated and review the audit reports to make sure that this part of the total quality system is alive and well.

The Quality manager must remember that even though everyone is responsible for quality, if he does not raise the flag on quality problems, his successor will.

GETTING IT STARTED

Timing

This review is not designed for crisis situations and should not be held during peak seasonal workloads. The period from mid-November to mid-January should be avoided to maximize the benefit. One to two months' warning of the scheduled review should be given, and the final agenda, covering 75% of the scheduled review time, should be in place at least two weeks before the review.

Selecting Participants

Since much of the outcome will be subjective opinions, the reviewers must have the respect of those in the Quality organization, as well as of people in the areas to be interviewed. The team should be diverse, with some specialists covering such areas as process and testing, while others should have overview experience. Interest in and dedication to this type of activity is mandatory for each reviewer. Consider possible conflicts of interest between the reviewer and the Quality organization to make sure that the review does not turn into an axe-grinding exercise.

For small companies, the use of respected consultants would be useful. Perhaps a trade with other noncompetitive companies could be arranged.

Motivation To Blast Off

Why should any Quality manager or sub-unit manager in his right mind subject himself to this kind of rigorous review? A flippant answer might be that, if he doesn't someone else will.

A more likely answer is that any organization which is not currently in deep trouble can substantially benefit through new ideas and approaches from this type of review. Substantial benefit comes from the internal preparation for the review and the questioning that goes on at that time. The second major benefit is the suggestions and observations of the review team based on their years of experience.

SUMMARY

A Functional Staff Management Review (FSMR) can easily be misunderstood. Let's look at some of its "is" and "is not" characteristics.

The Review IS:

- A peer evaluation of the entire quality system or subsystem.
- Results oriented.
- Based on professional judgement.
- Carefully planned in advance.

The Review IS NOT:

- An audit that each procedure is being followed.
- Activity or product oriented.
- By the numbers.
- A surprise.

LCS 020:70:400

MANUFACTURING PROCESS OPTIMIZATION
STUDIES --- THEORY AND USE

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INTRODUCTION

Manufacturing operations seldom approach perfection even though there is constant pressure for improvement in terms of tighter tolerances and improved yields. These pressures may arise from high internal losses, from customer complaints, from cost reduction programs, and from similar situations that bring out the fact that the process or equipment is not producing 100% good product. Sometimes the problems are obvious or easily discovered and corrective action may be taken. At other times the problems are not well defined or easily discovered and a "study" of the process is required. This paper defines, explains, and compares various studies that may be employed to achieve process optimization.

Eugene Grant⁽¹⁾ has pointed out that, "Measured quality of manufactured product is always subject to a certain amount of variation as a result of chance. Some stable 'system of chance causes' is inherent in any particular scheme of production and inspection. Variation within this stable pattern is inevitable. The reasons for variation outside this stable pattern may be discovered and corrected." The term "in statistical control" or more simply "in control" refers to variation within this stable pattern of chance causes. The term "out of control" refers to variation in excess of this stable pattern of chance causes. A stable system of chance causes is essential in determining process capability.

Many people have used the term "Process Capability Study" to describe a wide range of different process studies, each of which is a constituent of what may be called a process optimization study. In some cases the term "Process Capability" has been misused in the sense that a study based entirely on historical data, with no idea as to state of control of the process, may be a very poor indicator of the process capability. It is particularly important to be aware of the various elements of Process Optimization Studies when the conclusions reached from the study influence judgment as to the ability of the process to meet specifications or achieve a specified shrinkage rate.

COMPONENTS OF A PROCESS OPTIMIZATION STUDY

Considerable insight into the nature and intent of process optimization results from distinguishing four important components as constituents of a Process Optimization Study.

A Process Performance Check is a quick check of the product produced by the process being studied. It is based on a small amount of data taken at a given point in time. It gives a quick picture of process performance within a limited time frame.

A Process Performance Evaluation is a comprehensive evaluation of the product produced by the process being studied, usually based on whatever historical data is available. It gives a full picture of process performance over a period of time and can be used to estimate and predict potential process capability on the assumption that statistical control can be achieved.

A Process Capability Study is a study undertaken to actually achieve a state of statistical control on a process. It is based on current data taken over a period of time and includes efforts to bring the process into control. Assurance that the true capability of the process has been achieved can be made only when control charts have been run on the process for a period of time.

A Process Improvement Program is a comprehensive program undertaken to improve a process that is not capable of meeting specifications even though it is in statistical control.

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control. It includes engineering redesign of the process (possibly based on designed experiments) to improve the operation and the equipment so that the specifications can be met.

IMPLEMENTATION OF VARIOUS PROCESS STUDIES

Each of the elements described is implemented through the use of straightforward statistical techniques used to supplement and guide engineering know-how. They may be used separately or in combination to achieve process optimization.

1. Process Performance Check

This is a short-time check of the product produced by the process being studied (utilizing usually a week or less of most recent data). In the case of variables data this check tells where the process is centered and what its variation was at the time of the check. A simple frequency distribution, or preferably a probability plot such as the frequency distribution analysis sheet (FDAS) is a good statistical tool to analyze this check. With attributes data a knowledge of the overall percent defective and a breakdown of its components is usually all that is required. A Pareto analysis⁽²⁾ of the defects is a good approach for attributes problems.

Although some people may call a study of this type a "Process Capability Study" it really doesn't tell much about the capability of the process. This is because with such data there is no way to know if the process was "in control" at the time of the study and there is no way to know if the observed variation (or defect breakdown in the case of attribute data) was typical of the normal process. An estimate of process capability based on a Process Performance Check is likely to be far more useful than a foreman's guess or "engineering judgment". However, if there is variation in the process over time or if the process is out of control at the time of the check, the estimate of process capability may be misleading. A Process Performance Check is usually made by one person based on historical data.

This, the simplest of the Process Optimization Studies, gives important information about the centering of the process and some information about the process spread; or for attributes data a knowledge of the percent defective and a breakdown of its components at the time of the check. It can lead to quick corrective action with resultant savings. However, most process problems are complicated and are not likely to be completely solved by a Process Performance Check. Thus, while this check is useful and can lead to valuable corrective action, it alone is usually not enough to resolve most process problems.

2. Process Performance Evaluation

This is a longer term evaluation of the product produced by the process being studied (usually at least one full month in duration). Such an evaluation shows how the process has been performing in the past. Usually there is too much data for practical evaluation by a probability plot as in the Process Performance Check. Again, the Pareto analysis may be used to give valuable insight into attribute data. However, frequently the data is adaptable to control chart format (\bar{X} and R for variables data and P or NP for attributes data). This format is usually best for a study of this type.

Although a Process Performance Evaluation gives a broader basis to estimate process capability it is usually no more reliable than a Process Performance Check in that, without special attention, it is unusual for a process to run "in control" for a period as long as a month.

Sometimes it is necessary to estimate process capability from past data. If the data can be arranged in control chart form, a good estimate of true capability can frequently be made by eliminating the out of control points and estimating the process capability on the "in control" data only.

Inasmuch as this estimate of process capability is based on the assumption that it is feasible to bring the process into control in a technical and economic sense, an assumption which is not always true, it is not advisable to use this estimate of process capability to set specifications. When it is necessary to set a specification to the process capability, it should be done on demonstrated performance in terms of consistently attainable levels based on a careful Process Capability Study as defined below and not on a collection of historical data adjusted to be "in control". In general, specifications should be set to the users needs not the producers capability. In the

rare instance where the user must accept the producers capability as his specification this capability should be demonstrated capability not projected capability.

Being based on past data the Process Performance Evaluation is a fast yet thorough way to determine what has been going on (or wrong) in a process. It can lead to quick corrective action and thus to process improvement. While only a few process problems are simple enough to be resolved by a Process Performance Check many more processes may be optimized by the corrective action taken from a Process Performance Evaluation.

A Process Performance Evaluation is a more valid way of calculating the capability of a process than the Process Performance Check but suffers from two major drawbacks.

- (1) It is based on what "has been done" not on what "can be done".
- (2) The assumption that it is practical to eliminate out of control points may not be true.

A Process Performance Evaluation is usually (but not always) made by one person and is usually (but not always) based on historical data.

3. Process Capability Study

This is a study of current production, usually by means of control charts, whereby the true capability of the process is demonstrated. For processes involving variables data \bar{X} and R control charts may be used to determine the process centering and variation that can be maintained on a continuing basis. For processes involving attribute data P or NP control charts are effective in demonstrating the true process capability. For both cases the process capability is determined when the process is running in a state of control. Achieving a state of control might well involve engineering trouble shooting, establishing in-process controls, or tighter manufacturing supervision in the operation. It would not involve fundamental changes (improvements) in the process. Thus the "process capability" is the best performance that can be expected from the existing process running under normal "in control" conditions without any major expenditures for process improvements. A Process Capability Study, based on a process running in control, usually shows that significantly better process capability can be achieved than that estimated from a Process Performance Check or a Process Performance Evaluation. Being based on current data, usually taken over the period of time in which the process is brought into control, the results are not available as rapidly as the results of studies based on past data. Occasionally a Process Capability Study may be terminated before full statistical control is achieved if:

- (1) The cause and effect of the out of control condition is known and minor and its correction is difficult or expensive.
- (2) The process meets the specification even with the known out of control condition.

A Process Capability Study is frequently the most valuable of the Process Optimization Studies in that usually significant process improvements can be made at minimum expense. Every corrective action taken to achieve the true process capability also optimizes the process. In fact the process optimum is achieved only when the process is running at its true capability. While the Process Capability Study is usually inexpensive and results in yield improvement and cost savings, it requires skill and effort on the part of the study team. This skill and effort is directed at achieving an "in control" condition and developing process controls to maintain this condition.

A Process Capability Study can be made by one person but is usually a team effort. The team consists of manufacturing and QC personnel and frequently includes engineering.

4. Process Improvement Program

Sometimes, even though a process may be known to be in control because of existing in-process control charts or as a result of a Process Capability Study, the capability of the process is inadequate to meet specification requirements. In this case manufacturing and engineering changes designed to improve the process must be undertaken. This may include major expenses for new equipment, better raw materials, improved flow of material, etc. These changes organized in a formal agenda showing items to be worked on, priorities, responsibilities, and a completion schedule, constitute a Process Improvement Program. A Pareto analysis of the problem areas will show where to direct the engineering effort. Process Improvement Studies should be undertaken only after Process Capability Estimates are well established. Statistically conceived and

designed experiments may be required to show what actions will be required to correct the problem areas. The techniques of evolutionary operations (EVOP) may be desirable to move the process to an improved level. The control charts from the Process Capability Study should be continued to show the effect of changes made. A Process Capability Study optimizes a process to the process capability. A Process Improvement Program is required only when this process capability is inadequate to meet the requirements of the situation. The Process Improvement Program directs its efforts to improving the process beyond its present capability to a new higher level. A Process Improvement Program should be considered to be complete when the process is running at an acceptable rate, is "in control" and is producing product that meets the specifications with a scrap rate so low that further expenditures on process improvement are not justifiable. In concluding a Capability Study or an Improvement Program, it is important that continuing controls be instituted to insure that the problems do not reappear.

A Process Improvement Program is almost always a team effort. The team would usually include representatives from manufacturing, QC, and engineering. It might well be headed by a member of management. Such a program cannot be made from an engineer's desk or from a distant laboratory. It must be made by interaction with the process itself. It takes time. However, when a Process Improvement Program is properly performed the end result is a process capable of running in control, to the desired specification, at an acceptable rate.

SUMMARY--COMPARISON OF COMPONENTS OF A PROCESS OPTIMIZATION STUDY

The interplay of the four components of a Process Optimization Study may be summarized as follows.

A Process Performance Check gives a "snapshot" of what the process is doing at a specific instant of time. It can be made rapidly from existing data or from data taken at the time of the check. It is useful to give quick information about the status of an operation after a change or when a problem is first identified. Such a check is usually more valid than a supervisors guess or "engineering judgment" but it does not include variation over time and includes no information concerning the state of control of the process.

A Process Performance Evaluation gives a moving picture of process performance over a longer period of time. In fact this study gives the best information available about process performance when only past data is available. Since it includes more data, usually at least one month and sometimes all that is available, it takes longer to perform but gives a more complete picture of what has happened. If by chance the study was made during a period when the process ran in control, and this is not the usual case, the study would give a good idea of process capability. The Process Performance Evaluation should be used when it is important to know as much about the process as possible and it is impractical (usually because of time limitations) to do a Process Capability Study.

A Process Capability Study gives a "live presentation" of what a process can do when it is running properly. It gives an indication of the ability of the process to meet the specification. Process Performance Checks and Evaluations can be made by an engineer at his desk using historical data. The Process Capability Study involves current data and includes interaction with the process in an effort to get the process in control. This is a "hands on" real time study and the study team must include someone with intimate knowledge of the process. The pay-off of this effort is in terms of better process stability and improved yields. (Minor expenses in terms of maintenance, training, and trouble shooting are normal. No major expenses are contemplated in the corrective action stage of a Process Capability Study.) A Process Capability Study takes longer to perform and requires more work than a Process Performance Evaluation, but it is much more useful in that it includes interaction with the process over time and shows what the process is capable of doing and how it reacts to changes.

Ideally before a major process is turned over to production (by piloting or equipment development) a Process Capability Study should be run to demonstrate that the process and/or equipment is capable of:

- (1) Operating "in control" for sustained periods of time at an acceptable rate of speed.
- (2) Producing product within specifications.

A Process Capability Study should be run on an existing operation when an important dimension cannot be properly controlled or when scrap is considered to be excessive.

The dollar savings due to increased yields will almost always far exceed the costs of engineering trouble shooting and supervisory attention required in the study. As processes or equipment age or as requirements become tighter, it would be well to perform a Process Capability Study to determine the true capability of the process or equipment before making a capital outlay to redesign the process or order new equipment.

A Process Improvement Program should be considered only when the composition of the picture must be altered. That is, when a Process Capability Study has shown that the process can run in a state of control but cannot meet the product specifications with an economic scrap rate. Since this study is long term and likely to be expensive, the first step should be a cost analysis to determine if the potential benefits warrant the expenditures necessary to achieve them. Such a study may involve substantial expenditures to improve the process. Designed experiments aimed at resolving the critical process problems provide an excellent way to implement a Process Improvement Program. For some sophisticated processes evolutionary operation (EVOP) techniques or response surface procedures may prove to be the most productive method for implementing a Process Improvement Program. In cases where the required process improvements are obvious, the changes made should be monitored by a Process Performance Check after the corrective action has been taken. In any case, the control charts from the Process Capability Study should be continued throughout the Process Improvement Program.

CONCLUSION

When there is a need for process optimization and the corrective action is not immediately obvious, one or more of these studies should be considered. In a strategy for process optimization it is well to start at the earlier studies and proceed to the more complicated studies only as the need is demonstrated. A general rule, not to initiate a Process Improvement Program until a Process Capability Study has demonstrated the need for one, would frequently save money spent on process improvements when only process centering and adjustments are required. Proper use of these studies will identify the true capability of a process and effectively achieve process optimization.

ACKNOWLEDGMENTS

Many of the concepts contained in this report were developed in association with Dr. Edward G. Schilling, and his contributions to the theory of process optimization are most gratefully acknowledged.

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LCS 123:60:400

TEMPERATURE MONITORING & CONTROL SYSTEM FOR MLB'S

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INTRODUCTION

The product thrust of the General Electric Aircraft Equipment Division, Aerospace Electronic Systems Department, is in the area of complex high-reliability electronic systems for aerospace applications at the lowest possible cost. Our customers are placing higher and higher speed requirements on digital circuitry while eliminating the availability of cooling air. Designs require custom digital LSI, semiconductors, and microprocessors. These trends necessitate complex high density electronic packaging for our products. Therefore, the fabrication of complex multilayer boards represents a key manufacturing technology area. Typical designs average 14 to 16 layers and up to 4000 plated-through holes to provide electrical interconnections from one layer of circuitry to another.

Hence, the multilayer board fabrication area was selected for the first microprocessor technology application in Manufacturing. This would provide some of the controls necessary to successfully manufacture complex multilayer boards with increased specification requirements at reasonable yield. A temperature monitoring system was built to demonstrate the feasibility of computerized monitoring and control of chemical processes. The approach taken was to incorporate a microprocessor based microcomputer used for manufacturing process control applications.

INSTRUMENTATION AND CONTROLS

The first step was to procure chemical indicators and controls that lend themselves to direct data transmission. Since the temperature of the plating tank must be maintained within close limits, initial effort was concentrated in this area. Also, temperatures can be easily read and the outputs can be transformed into binary coded decimal (BCD) outputs. Hence, procuring instrumentation with BCD outputs would simplify the approach. It was determined that it would be advantageous to centralize indicators and controls where feasible. Fifteen chemical tank temperatures critical to the electroless and electroplating of printed wiring boards were selected. The chemical tank temperatures are monitored and controlled by digital indicators and controls located in two central consoles (see Figure 1). A microcomputer could then be directly wired to the central consoles for data collection and alarm reporting.

DATA PROCESSING REQUIREMENTS

It was understood that there are many chemical analyses which must be performed, but equipment is not in a state of development at this time in the entire field which lend themselves to direct data feedback. Therefore, it was assessed that any automatic data feedback system must eventually be married or interwoven with data taken from laboratory tests which are done manually. Figure 2 illustrates the overall system concept that evolved.

Chemical tank temperatures are automatically interrogated every hour during chemical operations and are recorded for two weeks in the temporary bubble memory storage existing in the terminal. Every two weeks or less this data is transmitted to a magnetic tape archival storage system resident on our Honeywell 66/60 regional host computer complex via a 1200 baud direct communication link or 300 baud telephone hookup with modem. Manual data is inputted into the terminal keyboard as required.

A Process Computer Systems Intel 8080 based microcomputer was selected for monitoring of the fifteen chemical tank temperatures. The mi-

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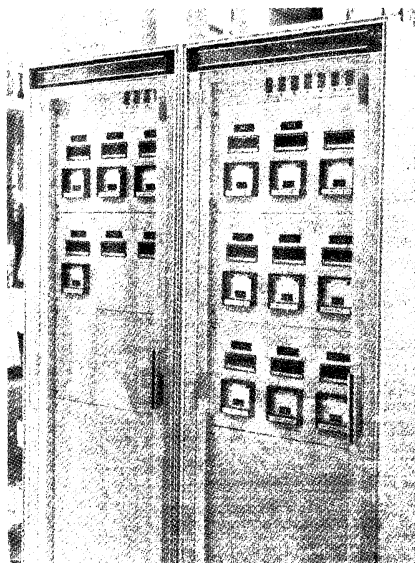


FIGURE 1. CHEMICAL MONITORING CONSOLES

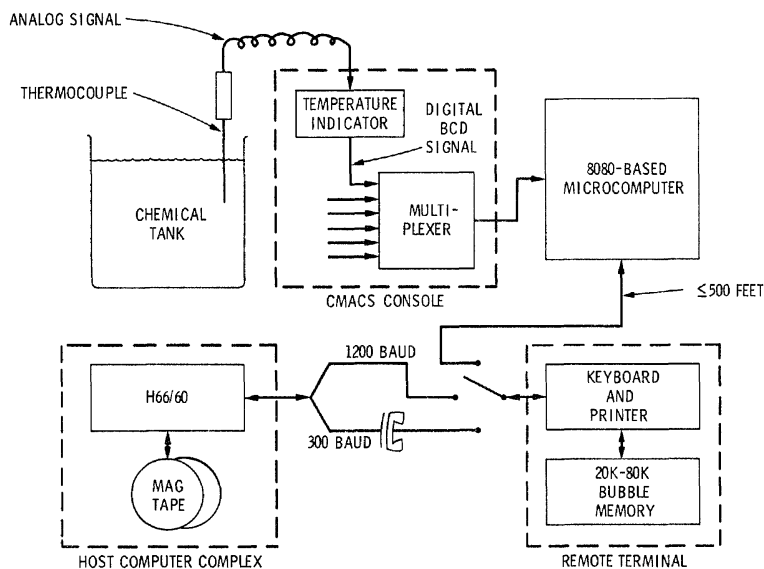


FIGURE 2. CHEMICAL MONITORING AND CONTROL SYSTEM (CMACS)

crocomputer selected has the capability of monitoring at least 40 points and controlling 24 points (see Table I). In the future, these points may control/monitor additional temperatures, pH, fluid level, or ampere hours.

A Texas Instruments (TI) 765 bubble memory data terminal was selected. It contains 20K nonvolatile storage, full ASCII keyboard, and a silent printer, with an acoustic coupler and RS-232 I/O ports.

TABLE I. CMACS TEMPERATURE MONITORING
TECHNICAL DATA

8080-Based Microcomputer - Process Computer System, Inc.

- 1K Bytes RAM
- 1K - 7K Bytes PROM
- Serial Port, 110 - 9600 baud
- Software Programmable Time Base Generator
- 40 Digital Input Bits
- 24 Digital Output Bits
- 8 Level Interrupt

MICROCOMPUTER TEMPERATURE MONITORING SYSTEM

Signals from fifteen indicators are multiplexed to a common 8-bit data bus and are addressed on a 4-bit common bus as shown in Figure 3. The microcomputer is controlled by the TI-765 data terminal which prints out any alarm condition and a temperature monitoring file summary.

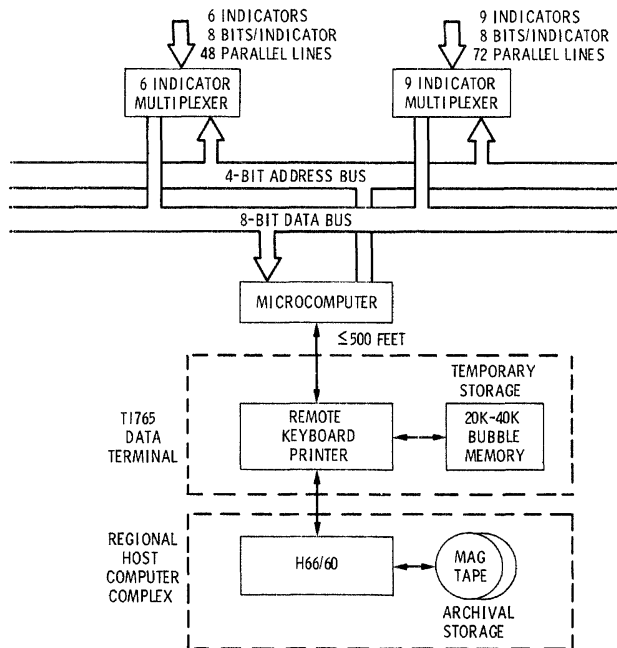


FIGURE 3. MICROCOMPUTER MONITORING SYSTEM

The temperature monitoring file consists of ASCII records. Records are separated by a blank line (two line feeds). A record header includes hour, day, fiscal week, and year of recording. The actual record lists the indicator number and corresponding temperature in Celsius (see Table II). Any temperature which is out of specification or out of preferred range is immediately printed out on an interrupt basis at the TI-765 printer as a warning. Data which is temporarily stored in the bubble memory and permanently stored into the archival magtape system of the regional host computer can be readily recalled into the time share system for further data analysis and trend plotting.

TEMPERATURE MONITORING TECHNICAL DATA

The unique interfaces and multiplexers required to tie together the microcomputer, digital instrumentation and terminal printer are as follows:

TABLE II. CMACS TEMPERATURE MONITORING FILE FORMAT

EXAMPLE:				No. Characters
24-53177	<CR>	<LF>		10
1 75	<CR>	<LF>	}	54
2 74	<CR>	<LF>		
3 74	<CR>	<LF>		
.				
.			}	42
9 75	<CR>	<LF>		
10 76	<CR>	<LF>		
.				
.			}	1
15 76	<CR>	<LF>		
<LF>				107

- Two multiplexers (MUX) which switch data lines from 15 temperature indicators to the microcomputer external bus (TTL → BUS) were designed and built.
- An interface card which interfaces the external bus to the TTL-compatible microcomputer (BUS → TTL) was designed and built.
- An EIA to 20 mA converter which interfaces the microcomputer to the TI-765 terminal (1200 baud maximum transmission speed) was purchased.

The microcomputer, and its associated interfaces, required for connection to selected digital instrumentation is illustrated in Figure 4.

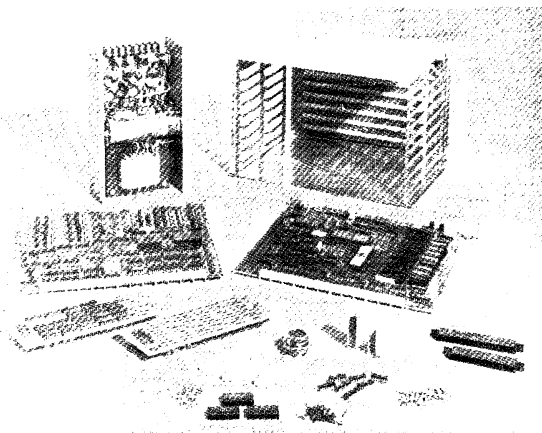


FIGURE 4. MICROCOMPUTER AND ASSOCIATED INTERFACES

TEMPERATURE MONITORING SOFTWARE REQUIREMENTS

Software routines were developed as follows:

Microcomputer Operating System Software

- 1K Monitor - Provides editor/debug commands which may be entered from an ASCII keyboard. Commands include display memory, fill memory, examine user stack register, and program

execute. This 8080 1K monitor had been developed for use on the Process Computer Systems' microcomputer by the General Electric Special Purpose Computer Center for general company use and was obtained from them in the form of an even parity 1K monitor source tape. An object tape was generated using an 8080 cross-assembler resident in the Regional Host Honeywell Level 66/60 time-share system. The object tape was edited and read into a PROM programmer to burn into a 1K 2708 PROM. Since this software activity had already been available, the software requirements for the project were significantly minimized.

- Real Time Clock - An initialization program sets clock time and a timer subroutine generates an interrupt every 10^{-2} second. The real time clock subroutine (Timit program) was taken from the Intel User's Library manual which was available in our Department.
- User Program - A record list program prints out requested records (example - see Table II).

Microcomputer Applications Software

- Temperature Monitoring System Program - A sensor scanning subroutine, and an initialization subroutine for file generation were developed.
- Limit Alarm - A program to print out a warning when specification or preferred range is exceeded and to extrapolate trend readings was developed.
- Download Program - This program loads data from the bubble memory into the time-share system.

Time-Share Software

- File Interrogation Program - A program for record retrieving in archival storage from any time-share terminal was written.

SUMMARY

By utilizing the resources already available and by incorporating a standard microprocessor, manpower and technical expertise requirements to implement the project were significantly minimized. In addition to improved process control, this investment will result in a payback in three years. But, what is much more important, a body of knowledge has now been developed within the Manufacturing organization which will enable expansion of microprocessor applications to other manufacturing areas for equipment and process control and monitoring where required.

CONCLUSIONS

The system as developed does provide real time process monitoring and control for selected chemical processes.

- Continuous control and digital display are provided for chemical tank temperatures
- A record is provided which shows that chemical processes are performed per specification
- Product uniformity and quality are increased by maintaining the proper chemical solution environment
- Operator awareness of chemical solutions is improved with the corresponding reduction in operating error, decreased rework, and increased yield.

As additional sensors become available, the value of the system will increase. It is anticipated that the equipment suppliers to the chemical processing industry will start to produce digital instrumentation and controls for a wide variety of measurements such as pH, specific gravity, and ampere minute/hour. These instruments and controls can

be readily connected to the existing microcomputer using the multiplexers and interfaces which have been developed. Also, all existing software modules can be utilized.

With the addition of specific software subroutines for each major class of instruments, this application can be expanded to a totally integrated real-time chemical monitoring and control system for most major chemical processing requirements.

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Contingency Table Analysis of Continuous Data

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Within an industrial or service environment, it is often technically and/or economically infeasible to implement the extensive production/ service testing of a characteristic using a specified measurement system. In these situations, an alternate measurement methodology is sought which is more compatible with the operating environment. When both measurement systems are continuous, a traditional prerequisite for the acceptability of the alternate system is that (a function of) the systems be linearly related and highly correlated. Suitable limits (cutpoints) for the alternate system can then be determined from the specifications using regression analysis.

In its Notice of Proposed Rulemaking on Section 207(b) of the Clean Air Act, EPA has proposed a contingency table approach of defining correlation and establishing cutpoints in those situations where the alternate system is continuous, but does not satisfy the usual requirements.

The following discusses the merits and applicability of this methodology with respect to good engineering and statistical practices. Examples are given based on the actual and simulated emission performance results of in-service vehicles.

INTRODUCTION

On May 25, 1977, the Environmental Protection Agency (EPA) published in the Federal Register a Notice of Proposed Rulemaking (NPRM) dealing with emission control system performance. In this NPRM, EPA asserts that the Clean Air Act requirements for short tests (ST) to implement Section 207(b) have been met and states that recently developed EPA "... methods and procedures are in accordance with good engineering practice and are reasonably capable of being correlated with tests conducted under Section 206(a) (1). ..." Section 206(a)(1) of the Act provides the authority under which emissions are measured according to the Federal Test Procedure (FTP).

This situation EPA faced in developing this NPRM is similar to that often experienced by people involved in production quality control/audit. The goal is to find a measurement methodology suitable for production application which is an acceptable substitute for a more desirable yet costly and/or time-consuming test.

When both measurement systems are continuous, as in the case of emissions testing, a traditional prerequisite for the acceptability of the alternate system is that (a function of) the systems be linearly related and highly correlated. This is ascertained by engineering analysis of the relationship assisted by an examination of a random sample of paired tests.

If a random sample of size n is drawn from a bivariate normal population with variables X and Y, then the correlation coefficient r defined by

$$r = \frac{\sum_{i=1}^n (x_i - \bar{x})(y_i - \bar{y})}{\left[\sum_{i=1}^n (x_i - \bar{x})^2 \sum_{i=1}^n (y_i - \bar{y})^2 \right]^{1/2}} \quad \text{and}$$

is a sample estimate of the population parameter $\rho = \frac{\text{Cov}(x,y)}{\sigma_x \sigma_y}$

The coefficient r is sometimes referred to as the sample product-moment correlation coefficient. This is one of the most commonly used measures of correlation.

However, EPA states "(i)t was anticipated that the short tests would not correlate with the FTP in a classical statistical sense, i.e., no short test is capable of a reliable and consistent prediction of the FTP mass emissions."

The proposed EPA rule further states that ". . .the Clean Air Act requirement of reasonable correlation. . . (will) be met if the short test is capable of reliably and consistently predicting whether the vehicle would pass or fail the FTP even if it cannot give the magnitude of the passing or failing margin."

Under this rationale, the continuous data should be dichotomized into pass (P) or fail (F) classes with respect to each of the tests. This will then yield a 2x2 contingency table as follows:

Table 1

		Pass	Fail	
		PF = E _O	FF	Fail
Federal Test Procedure (FTP)	FTP Std.	PP	FP = E _C	Pass
		ST		
		Cutpoint		
		Short Test (ST)		

where

PF = pass ST & fail FTP = E_O = error of omission

FP = fail ST & pass FTP = E_C = error of commission

CONTINGENCY TABLE CORRELATION

The 207(b) Support Document favors the use of a contingency table approach for determining correlation between the FTP and the short test because given a short test limit (cutpoint), the contingency table method can satisfy EPA's interpretation of the Clean Air Act requirement of establishing correlation between the FTP and one or more short tests, i.e., it meets the requirement of predicting FTP pass-fail. A measure of contingency table correlation is the phi coefficient.

$$\phi = \frac{(PP)(FF) - (E_C)(E_O)}{[(PP + E_O)(PP + E_C)(FF + E_O)(FF + E_C)]^{1/2}}$$

It can be shown that if the bivariate normal variables x , y are dichotomized, then ϕ is ρ .

The phi coefficient has a number of serious deficiencies, however. Carroll (1961) has shown that if either or both characteristics are dichotomized by cutting a continuous distribution into two parts, then the value of ϕ depends strongly on where the cutting point is set (see also Fleiss and figure 6). Thus, the correlation coefficient can be increased or decreased with arbitrary choice of cutpoint. For example, given 61 observations distributed in the following manner:

60 points in PP quadrant,
1 point in FF quadrant,
0 points in E_c quadrant and
0 points in E_o quadrant,

the correlation coefficient is equal to 1.0. However, if the short testcut point is increased so the vehicle in the FF quadrant falls in the E_o quadrant (i.e., passes the short test, fails the FTP), then the correlation coefficient is undefined (0/0).

Thus, by looking only at the correlation coefficient, in the first situation, the short test may be interpreted as an "excellent" predictor of FTP pass/fail but in the second situation, the short test is "horrible."

Although the observed contingency table correlation coefficient ϕ is the maximum likelihood estimate of ϕ under multinomial sampling, a further problem arises in determining the reliability of the sample estimate of correlation coefficient if one accepts the contingency table approach and uses such a coefficient as a measure of correlation between the FTP and the short test.

The approximate large sample variance of ϕ is

$$\sigma_{\phi}^2 = 1/n [1 - \phi^2 + (\phi + 1/2 \phi^3) * A - 3/4 \phi^2 (B + D)]$$

where

$$A = \frac{(R_1 - R_2)(C_1 - C_2)}{(C_1 C_2 R_1 R_2)^{1/2}}$$

$$R_1 = E_o + FF$$

$$R_2 = E_c + PP$$

$$B = \frac{(R_1 - R_2)^2}{R_1 R_2}$$

$$D = \frac{(C_1 - C_2)^2}{C_1 C_2}$$

$$C_1 = E_o + PP$$

$$C_2 = E_c + FF$$

To estimate the asymptotic variance from sample data, we substitute $\tilde{\phi}$ for ϕ , and the observed marginal proportions for the population values. Because $\tilde{\phi}$ is asymptotically normal with mean ϕ and variance $\sigma_{\tilde{\phi}}^2$, we can use $\tilde{\phi}$ and the estimated $\sigma_{\tilde{\phi}}$ to construct confidence intervals for ϕ .

In order to avoid ambiguity, a specific set of data has been selected for illustration purposes. Data on GM vehicles from the 1976 EPA Restorative Maintenance Program will be used. The description of this data is:

Number of vehicles tested: 102 (all vehicles test "as received")

Emission selected : HC
Short test selected : Federal 3 Mode - 30 mph
Units on HC for FTP : gm/mi
Units on HC for ST : ppm

This HC data has the following distribution:

- 81 points in pass-pass (PP) quadrant,
- 3 points in fail-fail (FF) quadrant,
- 4 points in error of commission (E_c) quadrant and,
- 14 points in error of omission (E_o) quadrant.

With this quadrant distribution, the estimate of the contingency table correlation coefficient was 0.19. At the 90% confidence level, an approximate interval estimate of the coefficient was from -0.02 to 0.41.

The maximum value of ϕ may be a value actually less than unity. Qualitatively, the more different the row and column marginals, the lower the upper limit on the absolute value of ϕ . Specifically, if the absolute value of ϕ were related to the error of commission E_c and the error of omission E_o , it can be shown analytically that for fixed E_c and E_o rates, ϕ is maximized only when the PP and FF proportions are equal. An example of the sensitivity of the maximum values of ϕ are to E_c and E_o are given in Table 2 for fixed $E_c = .05$.

Table 2

$E_c = .05$

E_o	Max ϕ	E_o	Max ϕ	E_o	Max ϕ
.00	.905	.11	.686	.21	.519
.01	.883	.12	.668	.22	.503
.02	.862	.13	.651	.23	.488
.03	.841	.14	.633	.24	.473
.04	.820	.15	.616	.25	.458
.05	.800	.16	.599	.26	.444
.06	.780	.17	.583	.27	.429
.07	.761	.18	.566	.28	.415
.08	.742	.19	.550	.29	.401
.09	.723	.20	.535	.30	.387
.10	.704				

CUTPOINT METHODOLOGY

Besides ϕ , EPA also discusses the following measures.

- (a) commission error rate $\frac{E_c}{E_c + FF}$
- (b) test rejection rate $\frac{E_c + FF}{E_o + FF}$
- (c) test effectiveness $\frac{FF}{E_o + FF}$
- (d) error of commission E_c

The following limit guidelines were also given for "acceptable correlation:

- (a) $\frac{E_c}{E_c + FF} < .15$
- (b) $\frac{E_c + FF}{E_o + FF} \leq 1.0$
- (c) $\frac{FF}{E_o + FF} > .5$
- (d) $E_c \leq .05$

A cutpoint would then be selected for a short test by an iterative procedure until one or more of the above were met.

A Monte Carlo Simulation study was conducted to determine the prediction ability of the different cutpoint methods. In particular, the study compared the prediction abilities of the error of commission set to 5% method to the short test rejection ratio set to 1.0 ($E_c = E_o$) method. For both methods, the short test and standard

tests were taken to have the same average and scale parameters. In effect, the standard test is being compared to itself by simulating back-to-back tests. This was done since the standard test itself represents the best possible (i.e., correlatable) "short test" and the effectiveness of the method can readily be determined.

The two tests are assumed to be log-normally distributed with a skewness of 1.2 and a coefficient of variation of about 40%. Different degrees of correlation (0, .5, .9) were investigated along with different levels of percent nonconformance (10%, 25%, 40%) on the standard test. To standardize the results to a general case, it is assumed that the limit value of the standard test above which all tests fail is 1.00. Although this simulation was designed to emulate the standard emissions test (FTP), the results are readily generalizable to any situation.

RESULTS

Results of the simulation for a correlation coefficient of 0.5 are shown in Figure 1.

ERROR OF COMMISSION SET TO 5% ($E_c=5\%$) METHOD - Based on the model assumptions, the theoretical short test cutpoint should be 1.00 and any variation from 1.00 is a measure of the error induced by the random sample distribution of the 50 selected paired data points.

Cutpoint Variation - For a given correlation, as the percent over the standard test limit increases, so does the value of the cutpoint. For a given percent over the standard test limit, as the correlation increases, the average short test cutpoint decreases. For the $E_c=5\%$ method and a degree of correlation of 0.5, the cutpoint ranged from 0.87 to 1.57 or 70% of theoretical correct value. This is quite substantial when one considers that the proposed methods would apply to all groups of vehicles regardless of the amount of correlation and percent over the limit. The highest cutpoint obtained was 1.98 with correlation of 0.0 and 40% over the FTP limit and the lowest cutpoint was 0.82 with correlation of 0.9 and 10% over the FTP limit. This is the total range of 1.16 or 116% of the theoretically correct value.

Cutpoint Coefficient of Variation - A measure of the variability of the short test cutpoint is the coefficient of variation. For this simulation, it varied from a minimum of 2.9 to a maximum of 9.0.

Error of Omission Variation - The range on the average error of omission in the sample was from 2% to 36%.

Variation in Fraction of Correct Predictions - The lowest average correct prediction is 0.59 and the highest is 0.93. For a correlation of 0.5 and a FTP nonconformance rate of 25% (25% over the FTP limit), the average is 0.77.

SHORT TEST REJECTION RATE SET TO 1.0

Cutpoint Variation - As shown in Figure 1, the average value of the cutpoint remains nearly constant at about 1.00 (the theoretical value) for all levels of correlation and percent defective, but the range of the cutpoint was from 0.81 to 1.59. This is a total range of 0.78 which is somewhat less than that for the $E_c=5\%$ method; however, with such variation, it still remains possible that all group populations cannot be treated equally.

Cutpoint Coefficient of Variation - The coefficient of variation for the cutpoint varies from a minimum of 2.4% to a maximum of 12.1%.

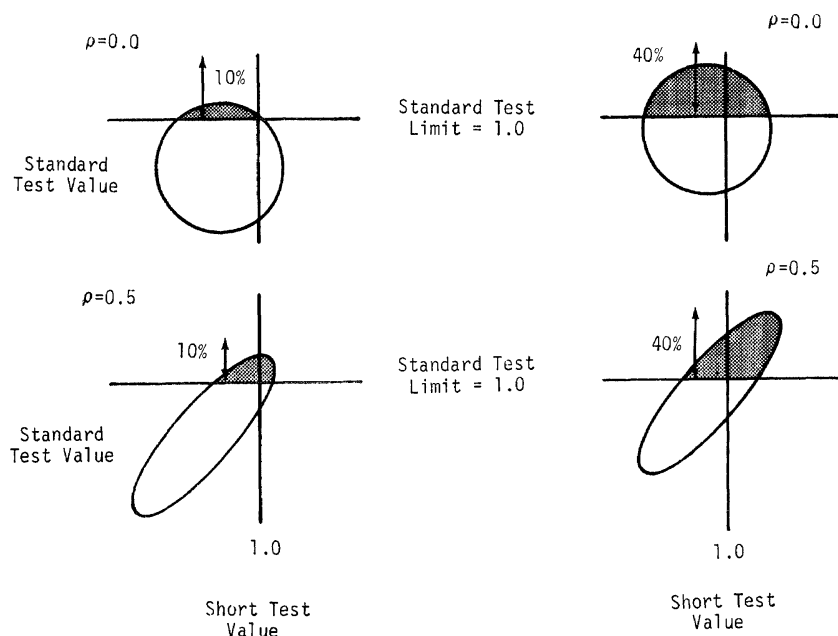
Error of Commission (or Omission) Variation - The range of the average error of commission (or omission) was from 3% to 24%.

Variation in Fraction of Correct Predictions - The lowest average correct prediction is 0.53 and the highest is 0.94.

Comparison of Cutpoint Methods - The rejection ratio set to 1.0 method consistently gives an average cutpoint close to the theoretical value of 1.00 whereas the error of commission set to 5% gives an average cutpoint substantially higher than 1.00 except

when the correlation is very high. To understand these trends in the cutpoint estimate, it is necessary to look at the integration surfaces. The diagrams in Figure 2 represent the boundaries of the integration surfaces.

Figure 2



With more correlation, the boundary becomes more elliptical. With a higher percent over the standard test limit, the percent of the short test distribution greater than 1.0 becomes larger.

For the error of commission set to 5% method, it can be seen from the diagram that a correlation of 0.0 and a percent over the standard test limit of 10%, the cutpoint will be greater than 1.0. With a percent over the standard test limit of 40%, the cutpoint will be larger than that with a 10% over the standard test limit. With a higher correlation, the cutpoint will decrease in value but still be larger than 1.00. Values less than 1.0 are obtained in the simulation due to the random samples being generated.

On the other hand, with the short test rejection ratio set to 1.0 method, the cutpoint values will oscillate about 1.0 due to the mirror symmetry of the boundary with respect to the 45° line through the surface.

Another significant difference between the two methods lies in the error of commission. While for the $E_c=5\%$ method, the error of commission was set to 5%, in the $E_c=E_o$ method, the error of commission averaged as high as 24%. This occurred with correlation to 0.0 and 40% over the FTP limit. Such high errors of commission are undesirable. On the other hand, if a high correlation (ρ) exists, such as 0.9, then the average error of commission will be in the neighborhood of 3-6% of the $E_c=E_o$ method, depending on the percent over the FTP limit.

Conclusion

The above discussion shows that for $E_c=5\%$, and $E_c=E_o$, the proposed methodology is highly erratic and dependent on the population characteristics. Figures 3 through 6 indicate the same is true for the other proposed measures. In general, only if the short test is highly correlated in the classical sense with standard test is the methodology acceptable; but if this is the case, the question naturally arises, why not use "traditional" regression techniques?

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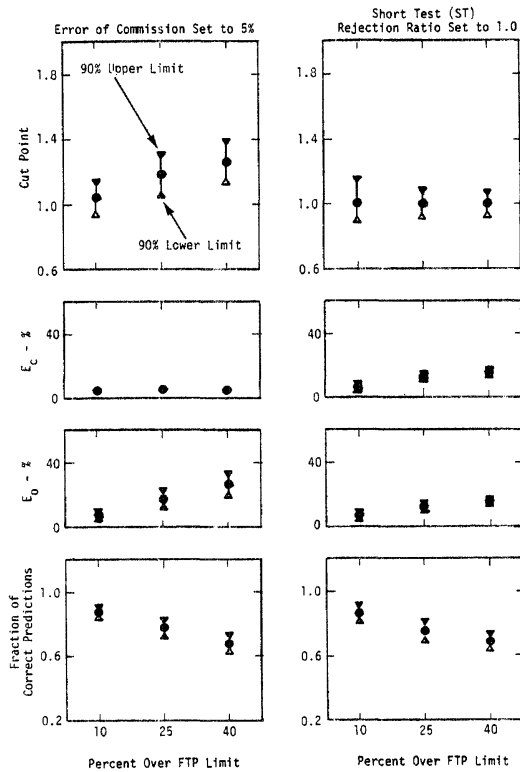


FIGURE 7
SIMULATED EFFECTS OF TEST VARIABILITY ON CUT POINT, ERROR OF COMMISSION, ERROR OF OMISSION AND FRACTION OF CORRECT PREDICTIONS FOR VARIOUS PERCENTAGES OF VEHICLES OVER FTP LIMIT WITH REGRESSION CORRELATION COEFFICIENT BETWEEN SHORT TEST AND FTP EQUAL TO 0.5

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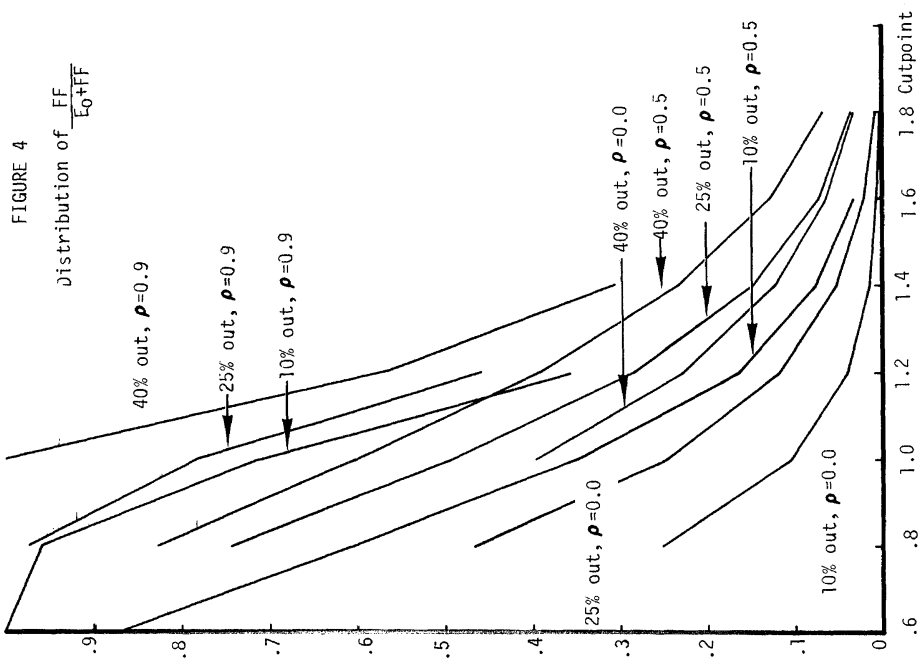
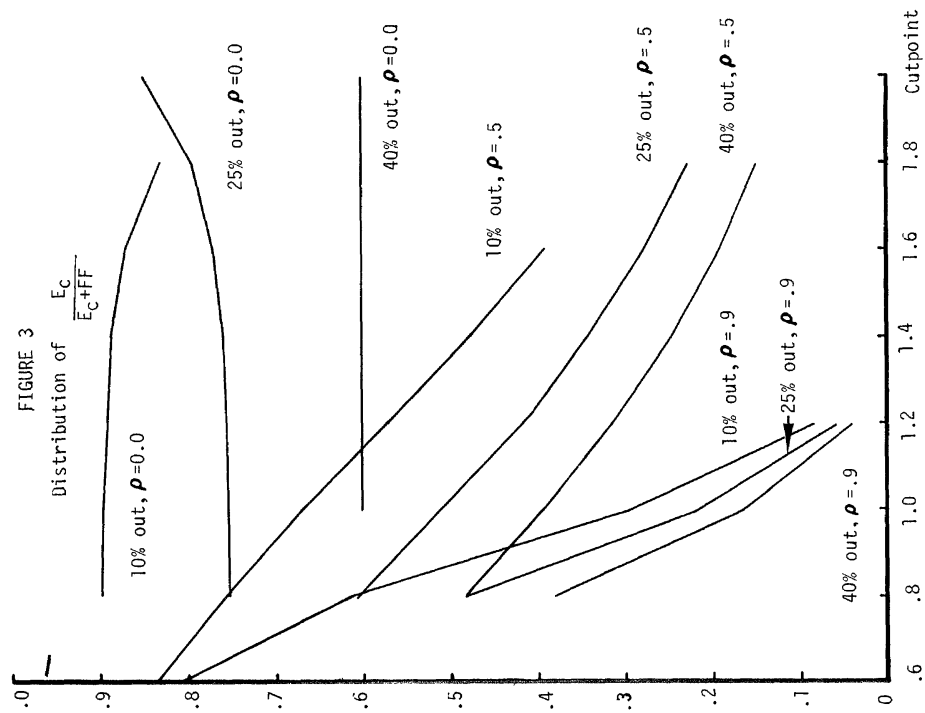


FIGURE 5
Distribution of $\frac{E_c + FF}{E_o + FF}$

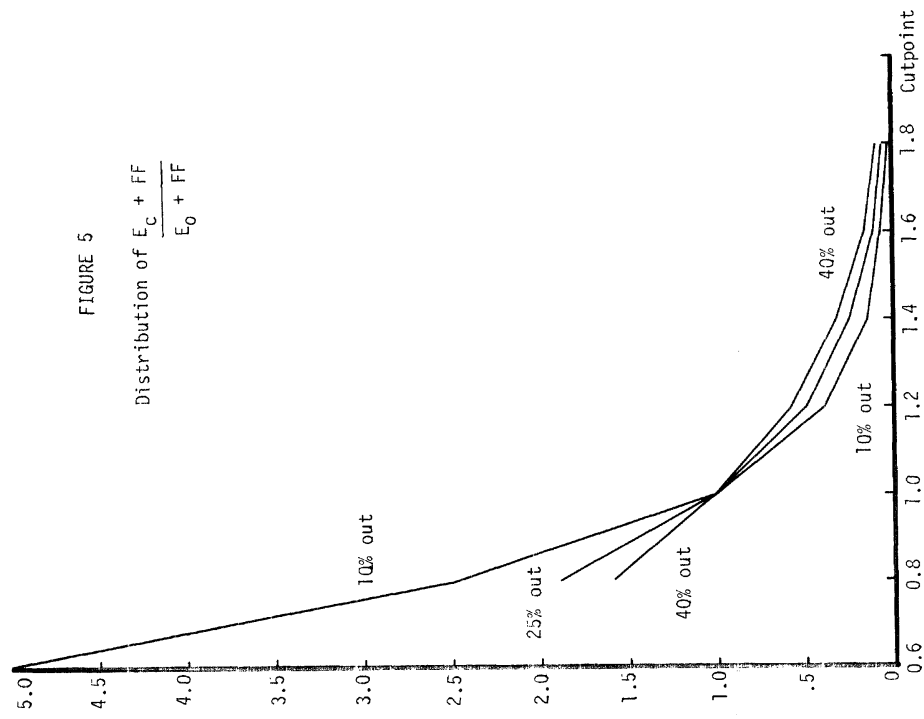
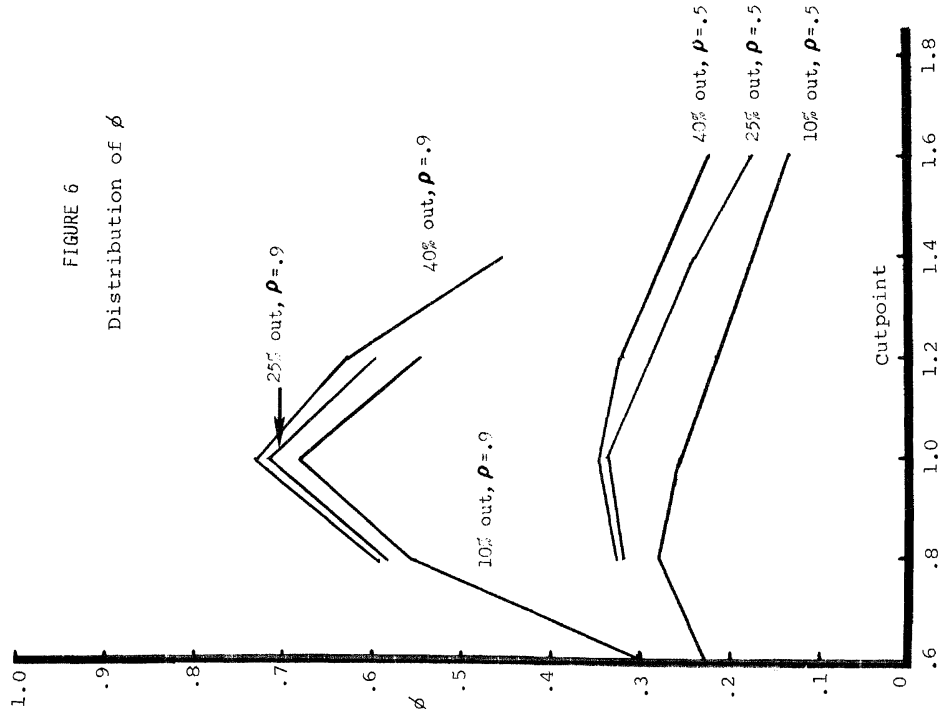


FIGURE 6
Distribution of ϕ



A SYSTEMS APPROACH FOR DEVELOPING SUPPLIERS

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Effectively controlling the quality of purchased material in automotive components manufacturing has always been a prime challenge to Quality Control professionals. No matter what technology they employ it seems that the results is always less than totally satisfactory.

Common among the systems tried are:

- (1) Receiving Inspection using statistical sampling methods and programed instructions.
- (2) Supplier certification.
- (3) Onsite (at the supplier) acceptance inspection.

The objectives of controlling quality of supplier material is well known. The principal objective is to provide assurance that materials we will input to the manufacturing process are functionally satisfactory. This statement translates into material which will not require off standard labor to use, create scrap, or contribute to premature field failures. Naturally, the buyer wants the value he contracted for, and for which he is paying the contract price.

Today when we setup a new manufacturing line, great care is taken to maximize productivity, control costs, control inventory, balance operations, control quality, and to provide a proper environment for the worker. This new line becomes an intergrated system with the foregoing listed elements, all interfaced and interacting. Great care is taken to program the quality control operations and to provide adequate test equipment. In-process test points are specifically identified. Final lot control inspections are structured.

The objective of the quality control can be described as being able to know from line supplied data what quality of product we have produced during the shift. If we truly know this quality, then we can say we know the quality of the material we ship and really meaningful quality control has been accomplished. There must be the capability to contain substandard quality product and to correct quality failures before the product is returned to the process or accepted as finished product.

The establishment of effective quality control in-process tests is made for any in-house fabrication.

When it comes to the material to be obtained from outside suppliers the intense programming of quality control technology in the supplier's operations is usually not undertaken. In other words, we expend most effort in-house to develop an effective quality control system, but seldom do we get that involved with the supplier. The most we do is process purchased material through a receiving inspection.

A SYSTEM APPROACH IS NECESSARY

A manufacturing system has an enviroment parameter of the facility that houses it. The system module has inputs of materials, labor, energy, and information. These inputs enter the assembly or manufacturing process where they are transformed. From the transformation process come outputs of finished product. From the stream of outputs flow comes feedback concerning the output to provide process control. Any supplier of part or component to the manufacturing system is providing an input to the production module.

The supplier in reality is operating a subsystem module in the manufacture of his part or component. This subsystem module is an input/output transformation process. When the output product becomes an input to the buying company's system, the two modules are interfaced and are interacting. Such is the case for every supplier to the major system.

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This situation should indicate that the prime manufacture should view the quality control applications in a total system module context. Further, he should adopt strategies to make his quality control applications a total system approach.

THE SUPPLIER MUST KNOW THE QUALITY HE IS SHIPPING

It is a known fact that suppliers who have the means of knowing in terms of significant data what quality they ship seldom cause the buyer a quality problem, and when they do, it usually is traceable to a design limitation. Such is not always the case. Small manufacturing operations may be planned to produce a part through a sequence of line operations completely devoid of any checking to confirm compliance to specification. Any feedback which would cause correction of manufacturing errors should originate with the buyer's operations. A sensing point this remote from the problem initiating point is of little value as an effective quality control feedback.

THE SYSTEM SURVEY

The system approach for developing suppliers requires that qualified Quality Control Engineers perform an audit survey of each contemplated supplier of material. The objective of this survey is to acquire knowledge of a source's quality control capability.

Information sought would include:

- (1) Management attitude towards Quality Control technology.
- (2) Management attitude towards making basic quality control costs expenditures.
- (3) Is there a Quality Control system organized and operational? Describe.
- (4) Company's organization structure.
- (5) Size of the company.
- (6) Type of products produced.
- (7) What technical expertise do they have?
- (8) Is there a problem of proprietary concern? How extensive?

The audit would provide means to pinpoint quality control deficiencies. The main concern is the supplier's ability to derive from his quality control system knowledge of the quality of the material he is producing, and the action he takes on nonfunctional quality when it is produced. When a survey reveals this type of deficiency existent in the system the survey report communicated the fact to the Purchasing department. In fact, each audit survey results in a report to Purchasing. Such reports will:

- (1) Approve the source as quality control approved.
- (2) Withhold approval until certain cited conditions are corrected.
- (3) Rejects the source as a supplier.

QUALITY CONTROL INTERFACE WITH PURCHASING

The closest coordination between Quality Control and Purchasing is required to initiate the system approach of improving supplier performance. The application of quality control technologies to supplier operations must come about because of Purchasing desire to have improve supplier performance. Purchasing breaks the ice with the supplier, initiating the request to the supplier for audit surveys, operating system changes, and makes disposition of all cost claims. Quality Control involvement is one of a technical expert assisting Purchasing in resolving system inefficiencies and deficiencies. Quality control must acquire expertise in handling sup-

plier relations so that Purchasing can have confidence in Quality Control. The representative working with the supplier's personnel without Purchasing personnel in attendance. Once such confidence is developed, Purchasing can derive many services from Quality Control. One such service is the onsite expediting of samples. Another is the conducting of educational seminars at the supplier's plant. Let it be emphasized, that there must be domination in all Supplier/Purchasing contacts by Purchasing for the system approach to improving suppliers to be effective. The strategy calls for doing a better job of developing suppliers and to expand the content of a company's quality control program.

INITIAL INSPECTION SAMPLE REPORTS (I.S.I.R.)

One of the key elements of the system approach to improving supplier performance is the requirement that the supplier furnish an initial sample. Such a sample produced from the production process demonstrates the process capability to produce the product. The requirement made of the supplier that he measure the sample as to its compliance to all engineering specifications, perform all performance tests, and to document the results, forces the supplier to become totally involved in his contract commitment. Disposition of the results is made in joint session with supplier representatives and buyer representatives at the supplier's location. An I.S.I.R. report accepted by the Purchaser's Quality Control is necessary for payment of the supplier's tool bill. The latter provides an incentive for the supplier to produce a good quality sample and to correct process problem at an early date.

The I.S.I.R. requirement forces the supplier to become acquainted with all specifications at an early time in his contract. It, also, forces the procurement of measurement capability in the supplier facility and training of a person to perform the measurement action. Such investment puts strength in the supplier's long term commitment to a meaningful quality control operation.

Frequently, processing of the I.S.I.R. will reveal non-compliance to the specifications. The purchaser's quality control representative can then assist the supplier in obtaining special disposition of such problem with the purchaser's engineering activity. Temporary deviations or corrective rework programs can be worked out to allow time for permanent correction and to supply parts to meet immediate requirements. This type of assistance to the supplier does much to establish a firm rapport between the respective quality control activities.

QUALITY PROBLEM REFERRAL

After the suppliers and purchasers quality control programs are fully operational a quality problem may occur in the purchaser's plant. When this happens, the problem is referred to the quality control activity. After investigation and identification of the problem, Quality Control will contact the supplier. The first order of business is to determine if a failure occurred in the supplier's quality control system.

Answers to certain questions are pertinent to taking corrective action. Is the incident a person failure or a process failure? Did the system sensing characteristics detect the failure? Why was the effected product not contained in the supplier's plant? What specific action needs to be taken to prevent reoccurrence? What action needs to be taken with the defective inventory?

The corrective action is concentrated on system failure correction when a quality problem is defined. The correction of defective inventory does not overwhelm all other concerns.

QUALITY ENGINEERING REQUIREMENTS

The quality engineering staff required to successfully implement a total quality control system with supplier must be comprised of high calibre personnel. Engineers should have education cores in technical engineering sciences. Further education in business management is preferred. Experience in Purchasing or Sales adds to the man's value. The engineer must like working with people and understand the problems and personality of the entrepreneur. Each engineer needs to have three years training in applying quality control technologies.

RECEIVING INSPECTION

A good functioning quality control program interfaced with the supplier's plants quality control will make receiving inspection a needless activity. The money saved

by not operating a receiving inspection activity can be used to pay for the operation of a quality engineering staff to be devoted to supplier services. Usually there will be a favorable savings even after the cost of quality engineering services are subtracted.

BENEFITS

Once the program is fully operational, certain programmed in-process performance tests become redundant and no longer necessary. Then the manufacturing process can be realigned. The cost savings can be significant.

An example of this, a major component supplied out of an industry with numerous competitors. Competitive bidding to obtain contracts had reached a point that significant quality control procedures were either eliminated or downgraded to a point of non-effectiveness in order to meet competitive pricing pressure. Consequently, the industry was shipping a significant amount of bad product. The purchaser was inputting such material into his manufacturing system and order to protect his build quality had to 100% test his product. Reject levels reached the forty-five percent level; repair cost escalated. In conjunction with Purchasing, and with the supplier's cooperation, a system analysis was made. Strategies were developed to correct the suppliers quality problem. The revision of the supplier's manufacturing system caused processing changes to take place where the cost factors offset or balanced out. The forty-five percent reject level dropped to five percent. At the new level of defectiveness the one-hundred percent level of product testing was no longer necessary and could be eliminated. Because the volume of production was high, extremely high saving could be realized.

SUMMARY

The system approach to improving supplier performance can be effective. To install and implement the program is time consuming. An added burden placed on Quality Control and on Purchasing. Improved supplier performance and better quality are the rewards for the hard work involved. The Quality Control professional should be pleased at the opportunities to advance the use of quality control technologies in the small business firm.

This approach to the control of purchase material quality may be the only way we can reach the entrepreneur and convince him that quality control should command his attention in planning his business operations.

LCS 351:40:439

RESULTS ORIENTED FOUNDRY QUALITY ASSURANCE

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For most companies, quality is a vital concern and an integral part of the overall production picture. At the Indianapolis Foundry of International Harvester, management has constantly sought to improve the quality of its castings, and to stress the importance of quality to workers.

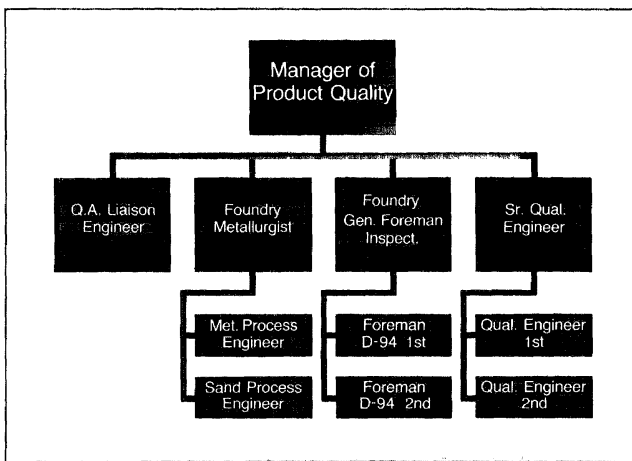
A program with those goals was started in 1974, and its results have been encouraging. Before the program could be developed and implemented, however; management had to take an in depth look at available equipment, manpower, and the quality group structure.

In some ways, the Foundry has not changed since the 1974 program was initiated. The Indianapolis facility is strictly a gray iron foundry utilizing electric induction melting with six 25-ton Brown-Boveri furnaces capable of producing 900 tons per day. Of the foundry's 400,000 square feet of floor space 110,000 square feet are occupied by core making activities. In the molding area are these four major Molding Units:

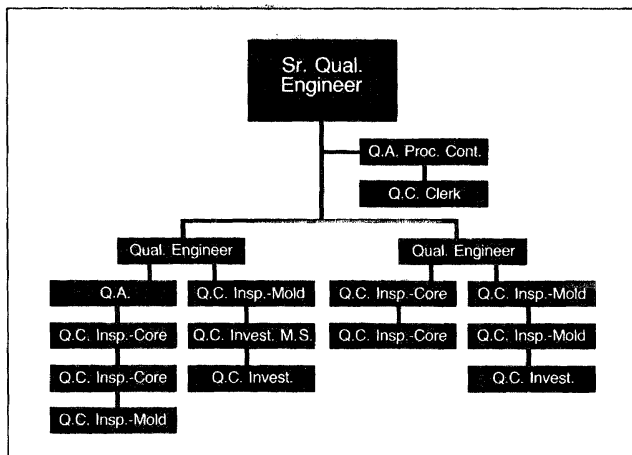
- I. Hydra-Slinger 38" x 51" - 16" over 12" at 75 molds per hour. The Slinger produces engine blocks, cylinder heads and housings.
- II. Spo Automatic High Pressure Squeeze 24" x 32" - 9" over 9" at 220 molds per hour. This unit makes cylinder heads, small brake drums and flywheels.
- III. Osborn Automatic High Pressure Squeeze 24" x 32" - 10" over 12" at 300 molds per hour. Intermediate size castings such as intake and exhaust manifolds, water pumps, oil pumps and flywheels come from this unit.
- IV. Spo Automatic Squeeze 51" x 38" - 12" over 14" at 200 molds per hour. The Spo Automatic Squeeze produces such castings as large brake drums, housings, and cylinder heads.

One event in 1974 that, to some extent, inspired the quality improvement program was the separation of the Foundry from the Machine Shop of the Indianapolis Plant. With the introduction of the Manageable Unit Concept at the Plant, the two areas, which previously had been managed as one entity, were divided into two relatively distinct sections. At that time, the foundry quality group was restructured and became directly responsible to the Foundry Manager.

Where there had previously been six management, six salaried, and 30 hourly employees, there were now 10 management, 18 salaried and 30 hourly workers, all of whom were utilized in a different manner.

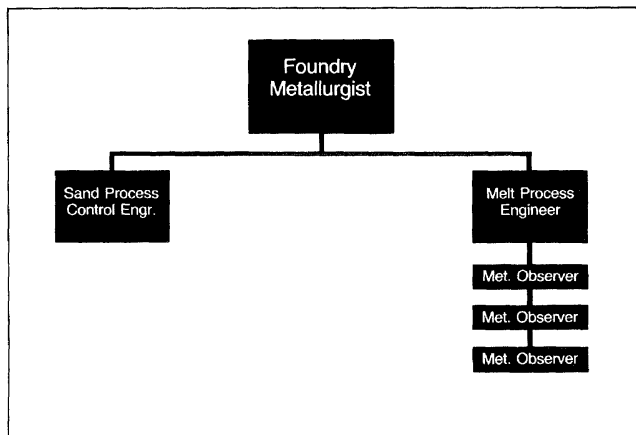


With the increase in personnel and the shift in responsibilities, new job assignments were necessary. The salaried group had to be structured to provide services for the production departments in day-to-day operations. They would also need to be utilized for documentation of procedures, performance of audits to identify discrepancies, development of records of performance, and statistical analysis work. A careful adjustment of personnel and assignment of duties resulted in this line up:



- I. One Process Control Analyst and one Quality Control Clerk to develop documents of procedure for all operations, from core making and cleaning to refractory coating and assembly, and including molding, pouring process times and temperatures, and any other procedures needed to produce a uniform, acceptable quality casting at minimum cost.
- II. Four Quality Control Inspectors (two per shift) on molding units, reading and recording iron temperatures, pouring times and mold hardness. They also were to sample metal superheat, and spot check cores and core assemblies at the unit.

- III. Four Quality Control Inspectors (two per shift) in the Core Room, auditing processes at the making, cleaning, refractory coating, and assembly of cores. Recording oven temperatures, measuring specific gravity, checking contamination of refractory coatings and miscellaneous checks as needed were also written into their job description.
- IV. Two Quality Control Investigators (one per shift) checking and following samples, auditing specific trouble jobs and investigating identified problems.
- V. One Quality Control Investigator who would serve as Machine Shop liaison.
- VI. One Statistical Analyst to keep records, reports, etc.
- VII. Three Metallurgical Observers to develop material standards and audit incoming material for conformance to specifications. These people were also made responsible for auditing the melt process and procedures, submitting reports and keeping records.



- VIII. One Steno-Secretary to serve the entire quality group as the need arose for communications, letters, reports and charts.

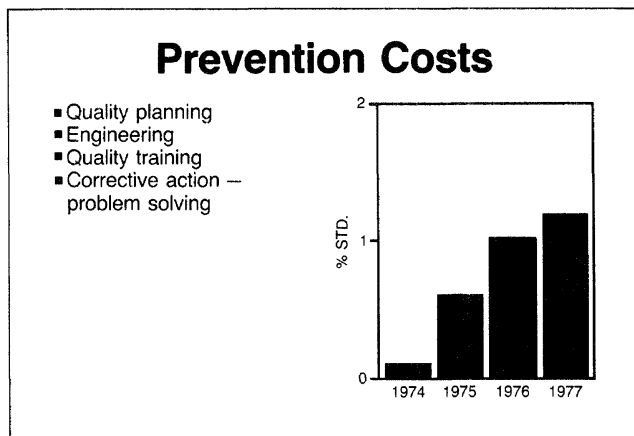
As with most changes, these increases had to be justified financially, using a method of evaluation new to International Harvester. The Corporate Quality Assurance group developed a systematic approach of measuring quality costs for internal comparison (plant to plant) and to use to monitor internal cost fluctuations. A three pronged total cost of quality concept, broken down into prevention, appraisal and failure costs, was agreed upon. These costs were measured against the standard cost of goods produced -- in our case, the standard cost of castings.

PREVENTION COSTS

Those costs associated with efforts to prevent and correct quality problems, reduce costs and increase customer satisfaction are Prevention. Such costs were incurred by product quality activities in these areas:

- I. Quality Planning and Engineering
 - A. General administrative reports
 - B. Pre-production evaluation and process capability studies
 - C. Quality control systems evaluation
- II. Quality Training
 - A. Both in plant and outside training programs which include quality control personnel and management, seminars, etc.
- III. Corrective Action - Problem Solving
 - A. Identification of and correcting the causes of defective material through such activities as process improvement, quality control audits and investigations, and reliability analysis, but not including activities concerning product disposition on non-conforming material related to scrap, rework, and salvage.

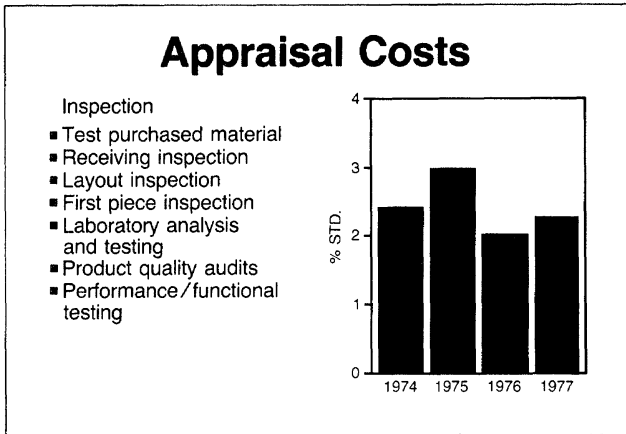
In 1974, .1 per cent of the standard cost of good castings was included in this prevention area. The following year, the area was expanded when some of the salaried group helped in the production area by documenting, evaluating and auditing. The Plant also hired a Quality Engineer to deploy their efforts, all increasing the cost percentage to .7 per cent.



Expansion of the area continued in 1976 when additional process documentation, audits, and evaluations with recommendations were added, and a Sand Process Engineer was employed. In 1977, the salaried Quality Control group took on still more responsibilities by completing process documentation and evaluating test results.

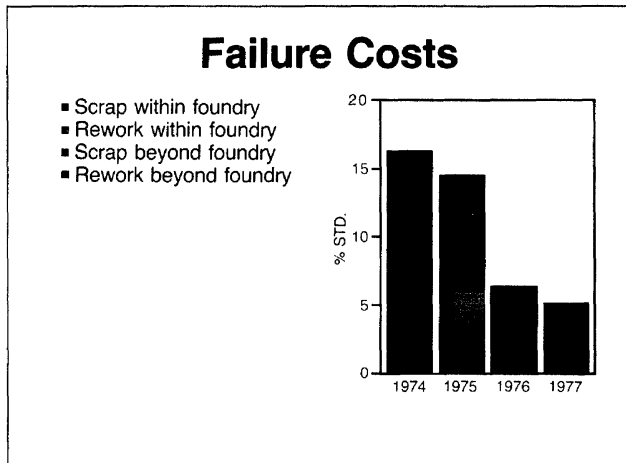
APPRAISAL COSTS

All inspection costs, whether they are incurred during the process, at final inspection, or in the reliability performance test, are Appraisal Costs. In 1974 about 2.4 per cent of the quality costs fell into this category, and in 1975 that figure rose to 3.0 per cent. Eliminating some of the in-process inspection in the Mill Room reduced the percentage to 2.0 in 1976, a level that held steady in 1977.



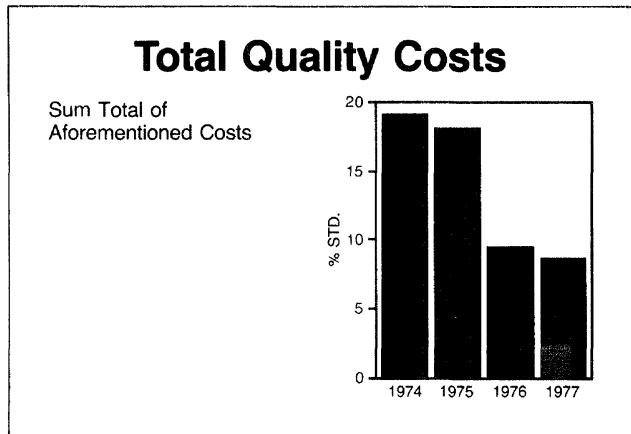
FAILURE COSTS

Failure Costs include the scrap and rework costs both within and outside of the Foundry. In 1974 those costs represented about 16.5 per cent of the standard cost of good castings, but the quality control program was effective in steadily reducing that figure. By the end of 1975 Failure Costs were down to 14.9 per cent, and were more than cut in half in 1976 when they were only 6.5 per cent. Failure Costs for 1977 were 5.9 per cent.



CONCLUSIONS

The International Harvester cost system for evaluating performance at the Indianapolis Foundry has proven to be very effective in showing the impact of quality costs as a business expense. Improvements made in the total quality cost area are readily apparent on this chart, which shows a decrease of 10 per cent in the standard cost of a good casting, from 19.1 per cent in 1974 to 9.1 per cent in 1977. This improvement has easily paid for the added 16 employees, and in addition saves the Company a large amount of money.



Taking a preventative approach to quality problems, rather than attempting to inspect quality into the product, seems to be working well for International Harvester's Indianapolis Foundry. Cost reduction results support management's view that during the four year period from 1974 - 1977 the Quality Control program really worked.

That success has pointed out a need for a continued and expanded effort in those areas not currently involved with evaluation and correction. The Indianapolis Foundry plans to meet that need, and to reduce total quality costs further to the 4 to 5 per cent range as soon as possible.

LCS 300:10:433

APPLICATION OF QUALITY TECHNOLOGY TO PUBLIC EDUCATION

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INTRODUCTION

Background

Public schools throughout the United States have received negative publicity regarding the quality of education provided to the local community. Declining test score values and comparative national averages are used as the indicators of the decrease in the quality of education provided. Educators generally denounce these claims, but investigations and assessments of the causes for such situations generally verify that little or no improvements are made which effect the quality of education.

Over the last thirty year period, the word "quality" has been associated with education and school systems as a positive descriptor of public education. Citizens are interested in the quality of education available to their children; hence, school officials continually use this word as justification for increased yearly funding and for requiring bond issues. The resultant costs of public education have now reached proportions of available public funds which cannot be met. In the past months, a number of Midwest school systems have closed because of the lack of funds. Costs for schools within governmental jurisdictions are between 65% and 95% of the total governmental budget. Recently it was reported that the cost per pupil for private schools was one-half the cost of public education with a higher quality of education received.

How effective are educational systems? On one hand, the citizens observe the results of education within their own children and are disillusioned when compared to costs. On the other hand, school officials continually offer greater "quality" to justify the increased costs. However, this word "quality" has not been defined and is used only as a descriptor.

There have been reports of school systems within this country where citizens no longer have a voice in their educational system. They are presented an ultimatum -- what is to be taught and the cost. Quality is not addressed. Public education is a local community responsibility and is under local community control -- or is it?

Definition of "Quality" as Applied to Public Education

The word "quality" in the English language has implied a qualitative characteristic which has assumed many different interpretations. As quality technology has advanced, quality has been defined generically and can be quantitatively measured. For purposes of this presentation, "quality" is defined as:

"...that level of education which is acceptable to the local community."

"Level" is defined by standards developed for each subject and grade level within the school system. The word "acceptable" generally is related to economic acceptability. This definition satisfies the general model of a quality program -- higher standards, higher costs; lower standards, lower costs. However there are minimum educational standards and there should be costs associated with these minimum educational programs which may be acceptable to the citizens within a local community, and which offer each student a "basic education" to meet lifetime objectives. The problem with this definition however is two fold: (1) there are no detailed educational program standards, hence no basis for measurement, and (2) there is no methodology applied to measure the uniformity of administration of standards across a school system. This combination is the basis for this technical presentation.

Equal Quality of Education

Over the past decade turmoil has developed within our school systems over "equal quality of education" for every child within a specific governmental jurisdiction. Is

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equal quality the question, or is "equal educational opportunity" the real question? Regardless, the problem is solved by legislation. By racial mixing of students from various schools together, legal experts indicate the quality of education will improve and that equal educational opportunity will result. Has it? This approach and rationale behind these decisions leaves a lot to be desired and there is a real question if every student in this country will receive an acceptable quality of education or if he will have equal educational opportunity. Today, the quality level of education which a child receives is a function of where he resides and which school he attends.

One will admit that school instruction and facilities tend to become segregated and polarized within school systems. Admittedly this is wrong; but do we make the quality for ALL students better by busing them to other schools and "so called" desegregation of the school system? It is implied within this approach that "quality" of education and equal educational opportunity will occur through legislation. Has the quality of education improved? Indications are that it has not. Has it degraded? Indications are that it has. Has a measurement system been developed to measure improvement of quality? No. Have educators attempted to develop more detailed standards by which to measure the quality of education? Have local educators asked the citizens of the local community what level of education is acceptable at a specified cost? No!

Education and educators plod along using the traditional techniques and methods of fifty years ago. Our systems are "clogged" with programs which are poorly developed and administered, and basic educational courses are suffering because of the "clogged" system. Educators should be concerned with improving the quality of basic education and be interested in developing a methodology for comparative measurement of the quality of various programs. Such an approach would improve the quality of the educational system, provide an equal quality of education to all students within a community (regardless of the quality level) and improve school-community relations by providing the opportunity to all citizens of "having a say" in their educational system.

Educators make the false assumption in analyzing test scores and in explaining the results that the quality of education provided in each classroom within the jurisdiction is the same, and that test score variations are due to the capabilities of the students. There is no effort to assess the cause of the variations nor quantitatively measure the quality of the education program offered which would validate the underlying assumption that the quality is relatively the same and that the range of score values is a true reflection of the range of capabilities of the students. If educators desire to interpret test scores and to use them as a basis for justifying costs of education, and of gaining community support, they must use valid assumptions -- that is, that the quality of education administered to all students was relatively the same and that each student had equal educational opportunity to learn. Only then can test scores be used to indicate that the student has learned in accordance with his inherent capability to learn.

THE APPLICATION OF QUALITY TECHNOLOGY

Developing Educational Standards

To establish a basis for quantitative measurement of quality, educational standards must be developed. These standards provide the "level" of quality in the quality definition. Course and curriculum standards are developed by educational "specialists" within the school system. Using a new fourth-grade math program as an example, let's examine the general procedure which is commonly used.

First, the math program is designed by educators schooled in mathematics. The program is outlined by the mathematics specialists, specifying the topics, educational objectives, and other unique characteristics to be considered. Secondly, media specialists provide recommendations for textbooks and other materials to be used. Audio-visual specialists provide inputs on A-V uses, materials, and suggested methods of presentation. Finally, facility specialists provide information concerning the required facilities to be used to enhance the learning process. Instructional specialists recommend the most effective methods to be used in presenting the course.

Thus all of the educational talent required to design and develop the instructional rationale, the materials to be used, and the facilities required to achieve the educational mathematics program for the fourth-grade has been developed. Normally, all fourth-grade teachers are then assembled for an "in-service training

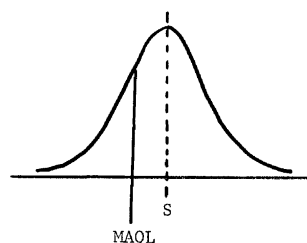
program" in how to present the program in the most effective manner in each classroom within the educational system.

It can be observed that no mention has been made of the Director of Quality Assurance. The Director of Quality does not engage in the design and development of the program. He may, if qualified and if asked, provide inputs which could make the program easier to administer, but in general he does not contribute to the course design. His role is to measure the uniformity or variance from the created standard across the entire school system.

During the in-service training of the teachers, the reliability (repeatability) of the developed prototype course may be measured to provide assurance that the instruction, materials, and facility requirements are practical, and produce the desired objectives within their functional limitations and constraints. The reliability of the course is the responsibility of the course designers including the responsibility for its achieving the objectives. Course reliability is a characteristic of the course design.

Administering the Course Within the Educational System

When the course has been designed, developed, tested and teachers trained in administering the course, the course is implemented throughout the educational system and becomes a part of the "standard" curriculum. As the program is conducted by the individual classroom teacher, the role of the Director of Quality Assurance becomes apparent. The objective of the Quality Assurance program is to "assure" or provide confidence to the Superintendent of Schools, the School Board and the citizens that the mathematical program is administered uniformly in accordance with the approved standard and that each student has equal opportunity to learn from it in accordance with his/her capabilities. The Director of Quality Assurance is responsible for assessing or evaluating each classroom and school mathematics program for variance from the standard.

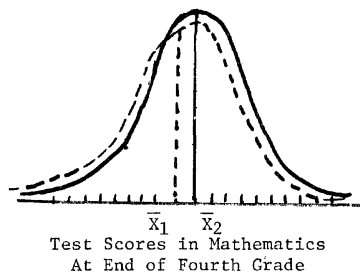
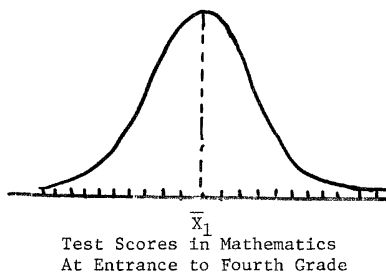


where... S = developed standard
MAQL = minimum acceptable quality level

The Director of Quality Assurance collects data on the variance of the application of the mathematics program in accordance with the developed standard.

Analysis of the Collected Data

Two techniques for measuring variance from a standard or mean (\bar{X}) value are the Range (R) and the Standard Deviation (σ). In a particular school system of 1800 teachers and 132312 students, test scores in a particular subject by schools had a range of from 32 to 71, indicating a large positive and negative variance from the standard. If the degree of variance from the program standard (instruction, materials, and facilities) were measured and correlated with test scores, there would be a high probability that the low scores were the result of a poor instructional and poorly administered program. This would be interpreted to mean that students in the classroom where the "poor" instruction took place did not have an equal opportunity to learn in accordance with their capabilities to learn as students in a class with "good" instruction. Wide variance of program administration relates to "poor quality;" small variance from the program standards results in "high quality" as described by the standard.



If a population of students whose capabilities to learn are normally distributed, and they were tested in mathematics at entrance to the fourth grade, and a mean score value obtained, the mean score value should increase at completion of the fourth grade if the students learned in accordance with their abilities and if the program was administered equally across the entire school system (minimum variance -- high quality). If there is a wide variance in the program administration within a number of classrooms, the mean value of the distribution will not shift in a positive direction. This is caused by students with a poor teacher not learning in accordance with their capabilities and this offsets gains made by students who learn in classrooms with good instruction.

Educators make the assumption that there is equal quality of program administration in each classroom and that mean test score values are not changing because of a student's capability. Of course, this assumption and interpretation is not true. To be able to correctly interpret the advancement in learning by administration of educational programs requires that a quality program be implemented within the school system and that the cause for students not learning be assignable -- either to capability of the student or to poor educational program administration. Past experience and evaluation indicates the latter in a majority of cases.

ESTABLISHING A QUALITY PROGRAM

Quality Technology

Quality Technology is subdivided into three (3) parts: Quality Engineering, Quality Control, and Quality Assurance.

Quality Engineering involves the design and development of a quality system for public school systems. The design is performed by professional quality engineers knowledgeable in public school operations. Quality engineers would probably not be employed by public school systems because of the scarcity of quality engineers and the minimal need by public schools. A quality model adaptable to public schools should be funded and developed by the National Institutes of Education and made available to all public schools. Such a model can be implemented and modified for a specific school system by professional quality engineering consultants. The model would include all procedures, instructions, evaluation criteria, techniques, etc. required to implement and operate a quality program within a public school system.

Quality Control is the operation of the quality system in accordance with the quality system design and the policies established by the school system and the community in accordance with the quality definition. Teachers, principals, supervisors, directors, associate superintendents, etc. operate the quality program in accordance with the design and often a training program involving its operation, responsibilities, objectives, etc. School system personnel, by their actions, maintain high quality education in accordance with the established standard (level) acceptable to the community.

Quality Assurance provides confidence that the quality system is being operated in accordance with the design. Quality Assurance is the responsibility of the Director of Quality Assurance for the school system. He continually conducts audits and assessments of the quality of education and provides assurance (confidence) to the Superintendent of Schools that a uniform quality level of educational programs is administered across the educational system. The Director of Quality Assurance continually supervises the audit, assessment, evaluation and measurement techniques within the school system and recommends corrective action to the Superintendent, when indicated by quality audits.

The Role of the Director of Quality Assurance

The role of the Director of Quality Assurance in a public school system is one of organizing, implementing and operating a quality program within the school system. The quality program should extend across the entire jurisdiction and may include application to the complete range of school activities, i.e. education, administration, construction, etc. depending upon the objectives and authority given to the Director of Quality.

Initially the Director of Quality should establish an operating rationale. This rationale is then converted into operating procedures which describe "how" the quality program functions and relates the techniques and methods to be used in conducting the quality assurance activities. Procedures, techniques, methods, organization, rationale, flow charts, data, etc. are all documented in a Quality Manual for the school system. It should be sufficiently detailed that it provides for continuous operation of the Quality Program regardless of personnel turnovers and/or changes in the school system organization.

The primary role of the Director of Quality is to measure quantitatively the variance of educational instruction, materials and facilities throughout the school system, between schools, and between all classrooms. Based upon the variance data obtained, the Director of Quality documents the conditions, analyzes the data, and makes recommendations to the Superintendent of Schools for any required corrective action. For example, data collected may indicate data points at extremes from the mean (\bar{X}) value of the distribution and an analysis indicates that poor instruction is the most probable cause. The Director of Quality should indicate that a possible problem exists. It is the responsibility of the Superintendent of Schools to take the corrective action, probably providing an in-service training program to improve the instruction. The major point is that the "Director of Quality" collects quality data, measures the variances across the school system, and recommends corrective action where and when indicated, but he does not become involved in the operation of the school system. Operating in an unbiased manner and using scientific approaches, the Director of Quality Assurance implies a degree of confidence to the school administration and to the citizens in their educational system and programs.

If the quality program extends into other school related programs such as administration, facilities, construction, etc. the Director of Quality should establish a quality program to control variances of activities within these areas in accordance with acceptable product standards. The primary activity of the Director of Quality Assurance is to provide confidence to the School Superintendent, School Board and the citizen taxpayer that the quality level to which they are entitled is being achieved and maintained.

PROBLEMS ASSOCIATED WITH IMPLEMENTING QUALITY PROGRAMS

Design and Implementation of Quality Programs

The development of quality program models for a specific school system is very expensive for an individual school system. If this concept is worthwhile and applicable to ALL public school systems, a model should be available which can be modified for specific school system application. Such a function is the responsibility of the National Institutes of Education and the Department of Health, Education and Welfare. If such a model were developed, the cost to implement a quality program for a school system would be substantially reduced. Such quality models would be developed by professional quality engineers.

Understanding the Quality Concept

If the quality concept is to be applied to public school systems, the concept together with the advantages must be made known to public school educators and administrators. Efforts to acquaint school administrators can be enhanced by the concept and advantages being described in publications which are directed to the school administrator. Organizations such as the American Association of School Administrators are excellent for disseminating the information. The American Society for Quality Control (ASQC) is the professional organization associated with the Quality profession and should begin to broaden the application of Quality Technology to other fields such as Education and Training.

Development of Quality Assurance Directors

If a Superintendent of Schools recognizes the advantage of a quality system, and if a model is available for implementation, the third major program ingredient is required. This is a Quality Assurance professional to operate the quality program within the school system. The approach being pursued to date proposes to develop Directors of Quality Assurance within a Master's Degree program within a School of Education within a University. The development of such professionals would be similar to developing public school administrators with MS degrees in Education. Some graduate schools of Education have expressed interest in developing such professional development programs.

SUMMARY

The Concept

The concept of applying quality technology to public education is a valid and worthwhile approach to solving some modern sociological and economic problems. In a modern society where everyone should have an equal opportunity to learn in accordance with their capabilities, it is mandatory that a system be established to achieve this democratic objective. Current public education programs are not valid in their assumptions. Trends seem to indicate that unmeasurable education systems can only be improved with increased costs, and these unrealistic approaches are reaching maximum limits of the American taxpayer. Therefore, the application of quality technology to public education can both improve the local communities economically as well as improve the educational system itself.

Implementation of the Concept

To implement quality programs within educational systems requires:

- Dissemination of the quality concept to public school superintendents and administrators.
- Development of a quality system model for Public School Systems funded by the National Institutes of Education.
- The development of Directors of Quality Assurance for public school systems through a graduate program in Schools of Education of our Colleges and Universities.

Conclusion

Much interest has been expressed in this concept. Some school systems have already implemented Quality programs -- some wrongly, but it is a start. Parents and teachers, school boards, and state public education officers have expressed interest in the approach to improving educational programs and opportunities. The American Society for Quality Control can assist in such a program by dissemination of information and providing assistance to American public school systems. Who can better promote the improvement of Quality of Education than the professional organization whose purpose is the Management, Engineering, and Scientific Aspects of Quality and Reliability -- applied to Public Education.

LCS 320:70:000

INITIATING PRODUCTIVITY MEASUREMENT SYSTEMS IN MIS

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ABSTRACT

Participative methods involving structured group processes have been utilized to begin the process of designing productivity measurement systems for computer based management information systems. The research indicates that the Nominal Group and Delphi methods, used for this purpose serve to establish favorable bases for completing the creation of productivity measurement systems. The research further indicates the composition of measures elicited by the participants suggest interesting contrasts between "traditional" efficiency measures and "non-traditional" effectiveness measures. Current research efforts stress the importance of strategies designed to operationalize the measures generated by participative methods.

FUNDAMENTAL ISSUES

Productivity, in general, is an elusive concept. It suffers from a historical background founded in misunderstanding, confusion, myopia, and rather uncreative and ineffective approaches to definition, measurement, and improvement. Traditional definitions, measurement techniques, and improvement strategies have neglected several important aspects of productivity:

- Productivity issues, for almost any system under study, are complex and thus multiple measures are required to convey the total picture
- Productivity means different things to different people and thus the more viewpoints involved, the more representative the productivity measurement system will be
- Productivity measurement and improvement can be attained through efforts to find the "right mix" of technical and behavioral techniques and methods for application in areas of concern.

Administrative computing and information (ACI) services have evolved with considerable rapidity, have undergone continuing evolution driven by high innovation rates in the underlying technology, and have quite often been imperfectly assimilated into the operating and management structure of the organizations they serve. With this in mind, research concerned with productivity measurement systems has focused on development of methods which incorporate the three above mentioned aspects.

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INITIATING DESIGN FOR PRODUCTIVITY MEASUREMENT SYSTEMS

The design and management activities for productivity measurement systems in ACI services should include the following:

1. Generating and weighting measures of productivity for the ACI system, utilizing all of the relevant viewpoints within the organization. These measures may be thought of as comprising a vector of measures which attempt to assess the efficiency and effectiveness of ACI systems from the viewpoints of
 - a. ACI service staff and operating management;
 - b. the various clients of the service, including those who receive it's information and documentary output, as well as managers whose decision making it seeks to enhance; and
 - c. the overall organizational objectives as embodied in the planning and decision making of top managers who determine ACI budgets and policies;
2. Specifying indicants of performance which could be used to assess the states of the selected vector of productivity measures(ie. an indicant is that which is used to assess the performance relative to a particular measure, for example, turnaround time as an indicant for user satisfaction);
3. Structuring the measures and indicants into a measurement system which determines which are presently available and which will require further technical assistance to bring into being;
4. Creating the necessary measurement instruments and methods required to bring the indicants into being leading to operationalization of the measures;
5. Executing a carefully designed program of implementation which will hopefully lead to an operating productivity measurement system available as an organization and management resource.

The "Right Mix" of Technical and Behavioral Techniques

Recent research and literature in the organizational behavior field has focused on the contingent nature of structure and process within organizations.(2) Concerns are raised relative to the influences of external factors(ie. environment), and internal factors(ie. structural features: size, shape, etc. and process features: authority, control, leadership, nature of group processes, etc.) on the performance of the organization, group, and individual. The basic concerns and interests lie with the nature of interrelationships among the factors.

Consideration of this research and literature might lead an organization, manager, or researcher to consider process issues relative to the creation of productivity measurement systems. The nature of productivity measurement systems as mentioned previously suggests that the process used to develop the system could be as important as the system itself, if not more so.

The classical approach to productivity measurement uses what might be called the consultation mode. This produces an expert-imposed system for measuring productivity. Results have been obtained with this ap-

proach, however, long term effective utilization of these systems appear to be of limited success. These traditional expert-imposed methods for measuring and improving productivity have focused primarily on technical solutions, ie., making operations more efficient. Efficiency measures tend to be relatively straight forward, inexpensive, 'objective', unobtrusive, and suited to portray only a very narrow view of the services 'real productivity'. Even for these measures, knowledge and communication of the productivity measurement has been limited to a few number of data center personnel. On the other hand, effectiveness measures tend to be relatively expensive, poorly understood, controversial, qualitative rather than quantitative, and 'subjective' rather than 'objective'. They are a strong function of one's perception of the purpose of the organization and they represent attempts to portray the 'real productivity' of the system.

An alternative to the consultation mode is a participative approach. A substantial body of literature and experience relative to participation and group processes suggests that there exists a great amount of untapped resources within organizations in the form of its employees. Groups can be used to make decisions, solve problems, generate alternatives, plan, design tasks, set goals and objectives, etc. Groups provide at least the following functional consequences:

- groups bring together knowledge and skills not possessed by a single individual
- the product of a group is more likely to be accepted by those who must act on it, than is the product of an individual
- there is a "group effect" through which group members learn from each other, stimulate each other, and supplement each other's knowledge and skills. The product of the group is in this sense greater than the sum of the individual contributions.

Groups, however, can also be accompanied by dysfunctional consequences such as time and resource consumption, inefficient operation, failure to act, etc.

The activities necessary to generate a productivity measurement system can be assessed relative to their inherent potential for use of group versus individual oriented strategies. This particular research believed there was a strong rationale for utilizing structured group processes for the activities of generating and weighting measures and indicants.

Two of the most widely known examples of structured group processes are the Nominal Group Technique and the Delphi Method.(3) The structured group process approach gives the consultant a low profile as a provider of methodology and strategy, rather than as a substantive resource for the group. Both the Nominal Group Technique and the Delphi Method consist of a set of clear, well defined activities. The process consultant may manipulate design variables such as composition of the group, size of the group, and nature of task statement in order to enhance the effectiveness of the process relative to the particular situation.

This research has investigated the application of two structured group processes, the Nominal Group and the Delphi methods. The work has been carried out at four large public sector organizations; two state governments, a city government and a public corporation employing some 30,000 people. Approximately 300 persons have been involved, investing roughly 1200 person-hours in the initiation of a productivity measurement system for ACI services.

The final steps in the process were not included in the original study(ie. steps 3,4 and 5), however, current research is concentrating on technical methods which can be utilized to accomplish these activi-

ties, which extend beyond the initiation of productivity measurement systems. The current research will be discussed, briefly, later in this paper.

The Nominal Group Technique

The Nominal Group Technique (NGT) is a four-phase process. The participants are physically present in groups of eight to twelve and the session is controlled by a process consultant or facilitator.

Following an opening introduction in which the purposes of the session are outlined, participants are presented a carefully worded task statement. For example, Task I in all of our studies was, "Please list below the important measures (indicators, criteria) of the productivity, effectiveness, or contribution of computing and information services from the point of view of your department or division." The group members are then instructed to write on the sheet provided, their responses to the task statement. The first phase is called silent generation and typically takes about ten minutes.

Next comes the round robin phase. The facilitator calls on participants one-by-one to state one of the responses he or she has written. Participants may pass at any time and join in on any subsequent round. A participant may propose only one measure at a time and either the facilitator or an assistant records each item as it is offered. (A large easel is ideal since all items must be in full view of the group for the remainder of the session.) The only discussion allowed is between the facilitator and the participant who proposes the item and it is limited to seeking a concise rephrasing for ease of recording. Participants are encouraged to add items to their personal list should new ones occur to them during the round robin.

The third phase is called clarification. Once all items have been recorded, the facilitator goes over each one at a time to ascertain that all participants understand the measures which have been recorded. Any participant may offer clarification or may suggest combination of similar items, however, no evaluation is permitted.

In phase four, voting and ranking, participants are provided with eight blank cards. Each must now select eight preferred measures and write them, one per card. Participants then spread the eight cards such that they can be viewed simultaneously. Working alone, each selects the single most preferred item and writes the score 8 on the card, and puts it aside. Of the remaining seven cards, the least preferred measure is selected and scored, 1. This iterative process continues until all are scored.

During a short break results are compiled and the scores are recorded beside the items on the clarified list at the front of the room. The resulting consensus measures are discussed. The entire process should require about two hours.

The above process is used to generate and weight measures and indicators. However, specification of indicators does not require phase four of the NGT process.

The Delphi Method

The Delphi is a methodology for the systematic solicitation and collation of judgements on a particular topic through a set of carefully designed sequential questionnaires interspersed with summarized information and feedback of opinions derived from earlier responses.

These sequential questionnaires are used to obtain information or opinions from a group of experts; the respondents. One important feature of the Delphi is that the participants never meet face-to-face, since the questionnaires are usually mailed. For this reason, group members retain their anonymity throughout the process and any negative attributes of most group techniques, ie. dominance, interpersonal conflict, are avoided. Additionally, unlike the Nominal Group Technique

the Delphi does not require movement of people in order to accomplish the task objectives. The Delphi represents a tradeoff of cost and time relative to the Nominal Group Technique. The Delphi can usually accommodate larger numbers of participants at a lower cost, whereas the Nominal Group Technique can usually be completed in less time.

Both the Delphi and the Nominal Group Technique were used to accomplish the generation and weighting steps. That is, the task statements for both processes were identical, only the nature of the structured group process differed.

The typical results from the research sites can be seen in figure 1.

<u>Results of Activity 1</u>		<u>Results of Activity 2</u>	
PRODUCTIVITY MEASURES:	Votes Received	Total	"HOW TO MEASURE, HOW TO ASSESS, WHAT ARE THE INDICANTS?"
<hr/>			
The degree to which the data center meets the defined needs of the users	7-7-7-8 6-6-8-8	57	Number and type of complaints; Percentage of information that is relevant; etc.
Responsiveness of the data center to problems, complaints and inquiries	6-6-7-5 6-7-6-5	48	Percentage of repeat complaints; Time from complaint to solution; etc.
Degree to which data center coordinates and communicates with vendors, users, and within the data center itself	6-5-5-5 8-8-4-5	46	Percentage of users aware of data center capabilities; Number of user-data center meetings; etc.
Ability to update and keep current the information system	5-5-7-4 4-3-4-4	36	Time required to update; data entry capacity; etc.
Timeliness of output and information	4-4-3-3 2-2	18	Time needed versus time received; percentage of user deadlines met; etc.
etc.			etc.

Figure 1.--Exemplary Consensus Measures from Research Sites

WHAT CAN BE EXPECTED FROM APPLICATION OF STRUCTURED GROUP PROCESSES FOR INITIATION OF PRODUCTIVITY MEASUREMENT SYSTEMS ?

Research results indicate that generation and weighting of measures and indicants can be successfully accomplished utilizing structured group processes. The overall quantity and quality of the measures is comparable to any expert generated list. However, the expected advantages of participatory approaches cannot fully be acquired unless the organization attempts to complete the activities as outlined earlier. It is believed that certain factors contribute to an organization's inclination to continue the development of productivity measurement systems beyond the initiation stages. Probably the two most significant factors are the general salience of productivity assessment and the stage of growth of the ACI system.(1,4) The previous research also produced several important insights relative to the nature of productivity

measures generated from participative methods:

- there appeared to be considerable ambiguity within organizations relative to the nature of or mere existence of productivity measurement systems. There was no clear productivity measurement program in any of the organizations studied, although certain "traditional" efficiency measures were monitored (ie. downtime, turnaround time, reliability, etc.).
- the consensus measures across research sites reflected a heavy emphasis on what might be termed "non-traditional" effectiveness measures. (ie. user satisfaction, degree to which data center meets users needs, etc.) Approximately 50% of the measures were of this category, and those measures were most frequently among the top four consensus measures for each participating group.
- approximately one-half of the indicants (activity 2) were judged to be ready for incorporation into a measurement system with little or no modification (that is they were operational).
- much of the concern for conflict and lack of consensus regarding measures and indicants for productivity appears to be attributable to point-of-view discrepancies arising from differing positions within the organization. The group process appears to have a remarkable ability to provide an opportunity for heterogeneous groups to reach consensus regarding the components of a productivity measurement system. The process can additionally be used to separate and prioritize measures relative to various perspectives within the organization.
- basic difficulties regarding taking a productivity measurement system beyond generation and weighting appears to be attributable to hierarchical structure of measure-indicant relationships. For instance, user satisfaction can be a measure for which turnaround time may be considered an indicant. However, turnaround time may be considered an independent measure in itself. It appears that these major issues need to be researched.

BEYOND INITIATING PRODUCTIVITY MEASUREMENT SYSTEMS

Generation of consensus measures and indicants which represent timely organizational values, concerns, conflicts, agreements, etc. is a major step in the direction of generation of a useful and effective productivity measurement system. It is a step which few organizations have taken or are capable of taking. Therefore, we believe this research has been a contribution to the field of productivity research as well as to applied productivity concepts.

An organization's willingness and interest in assessing and improving productivity is a necessary ingredient for generation of a completed productivity measurement system. Assuming this ingredient exists, it is believed that utilization of the methodology described in correlate research publications (1) will provide any organization with the basis for a productivity measurement system for ACI services. Once completed with

initial activities any organization faces implementation issues. The organization may choose to; do nothing else, utilize the results in a segmented fashion (ie. benefits and applications accrue to individual departments in form of ideas for improving communication between users and providers, ideas for centralization versus decentralization decisions, etc.), utilize the results to form the foundation for a productivity assessment system, utilize the results to form and derive a productivity improvement system. The activities required to utilize the results of initial activities for development of more sophisticated productivity assessment or improvement systems have not been clearly formulated as of yet. However, current research has begun to focus on use of multi-attribute utility models in order to aggregate productivity measure assessment into one number which might be thought of as a productivity index. Other research concepts focus on the need to consider the productivity measures and assessment indicants as a non-collapsible vector of productivity. These concepts infer that decision makers would achieve insight relative to areas for improvement as a result of observing the evaluation of the measures in a prioritized vector format.

It is likely that the most successful strategy for productivity assessment and improvement will be one that is tailored to each organization's special needs. Therefore, much of the present concern is directed at identifying methods which allow individual organizations to design their own specific productivity assessment and improvement system. The foundation for progress in the area of productivity assessment and improvement has been laid. It is desirable for industry, government, and academia to continue to strive to work together in this endeavor.

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THE MANAGEMENT INSTINCT

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Management is more an art than a science, but the effective manager is both a practicing social scientist and an artist. He is sharply differentiated from the scientist or artist because the scientist observes and records his findings, while the manager goes one step farther and takes action. The artist need only express his thoughts or feelings and he can ignore public taste, but the manager, working with other people's capital, other people's labor, and other people's material must consider the public's opinions in order to make a profit and survive.

Intelligence, good judgement, analytical ability, energy, etc., are all important to managerial success. They are also important to success in all professions.

A recent report contained a consensus on managerial traits. They were: 1) initiative, assumption of responsibility and leadership, 2) job knowledge and skill, 3) dependability, thoroughness and follow-through, 4) getting along with people, 5) stability under pressure, and 6) fine personal qualities and work habits.

Another magazine listed the five most needed traits as: 1) ability to be flexible and adapt to accelerated change, 2) ability to be imaginative and to innovate, 3) proficiency in controlling and reducing expenses, 4) ability to mobilize and motivate men, 5) skill in coordinating and correlating forces within and outside your company.

The legal mind is committed to the abstract ideal of justice. It is interested primarily in what and how something happened, and secondarily, in why it happened.

The scientist is dedicated to a systematic knowledge of the general laws governing the physical or material world.

The religious individual is absorbed with spiritual values and the relation of man to a supernatural being or to an eternal principle.

The educator is interested in developing the special and general abilities of the mind by imparting particular knowledge or skills.

The businessman-owner is concerned primarily with profit.

The engineer working within the organization is involved primarily with creating a specific product. He is not normally concerned with other people's problems or with the larger problems of the organization.

The stockholder is primarily interested in the organization as an investment. If the growth and yield of his stock is satisfactory, he is content. The internal workings of the organization only concern him when they affect his investment.

To the manager, however, the organization is an end in itself. He is totally committed to it. He gives his loyalty in return for the power, prestige, security, and money it gives to him.

The organization is important because it exists, he may disagree with specific policies or with people within the organization, but he will try to effect changes within the existing structure and will not attempt to destroy it. There is in this attitude towards the organization, a potential source of trouble; for the manager is sometimes torn between his own personal values and his loyalty to the organization when its values conflict with his.

One cannot manage effectively without power. Yet the exercise of power tends to alienate people. The effective manager will use his power discreetly and judiciously, never employing more than the situation demands, yet never hesitating to use it fully when appropriate. He accomplishes his will by persuasion, suggestion, example, but he knows, and his subordinates know, that such techniques are effective, at least partially, because of the power of his position.

Since the manager's commitment is to the organization, he must use people as means to an end, that is, to effect organizational goals. He may temper this harsh reality with tact and discretion but he knows that the organization comes first and that the individual is expendable. Such a realization is a breeding ground for resentment and poor morale, and he may suffer strong feelings of guilt if he is capable of genuine emotional sympathy and if forced to sacrifice an individual for the company's good. This indicates that probably the most successful top executives are characterized by a basic emotional coldness with an external ability to get along with almost anyone.

The manager runs the risk of perpetuating his own errors because of his authority. He needs to have sufficient power to enforce his decisions; but, he must always keep in mind that many things are done his way because of this authority and not always because he is right. He should not only be able to evaluate criticism leveled at him by others, but should anticipate such criticism by objectively examining his own actions on a continuous basis.

Self-confidence, aggressiveness, and a strong personality are definitely managerial assets, but he must be careful of stifling his subordinates' initiative. He should realize that by virtue of his position, he is the authoritative father-figure to his subordinates, and, as the father, wishes his sons to grow up strong and independent. The manager, wishing to develop his subordinates to their fullest potential, must let them develop confidence.

This emotional atmosphere enables him to detect potential problems. Having utilized his sensitivity to determine where the problems lie, he must use his judgement and take action on the basis of what is best for the organization. In other words, he may have to act ruthlessly.

The conflict between personal ambition, loyalties, and ethics and organizational demands may lead to strong feelings of guilt, anxiety, tension, and frustration. For a man whose loyalty is to the organization may have to act against the dictates of his temperament, his sympathies, or his values when the occasion arises.

A manager may be deeply involved, both emotionally and career-wise, with a company that has provided him with meaningful work, material rewards, good friends, and psychological sustenance. Then another company offers him a job with far greater rewards and potential. His loyalty urges one course of action while obligation to his family and his own future urges another.

Use of people tends to dull the sensitivity to people's "private" feelings. Such human worries as love, death, aging, insecurity, morals, etc., are not of interest to him unless they affect organization in some way. His use of people in the name of organizational goals, tends to restrict his concern for the problems of others when they intrude upon organizational efficiency.

He tends to be uncomfortable with broad social problems which do not lend themselves to quick, direct solutions. He tends to favor the practical, down-to-earth, immediate solutions over the theoretical ones. Actually, the goal and results-oriented manager prefers the imperfect, short-range, interim answer to waiting for the ideal, long-range one.

Such an attitude is forced upon him by his job. His work is never done. The problems that confront him are recurrent; he solves one problem so that he may go on to the next. He is engaged in an endless struggle with the powerful disruptive forces which are always active in an organization -- personal animosities, jealousies, rivalries, misunderstandings, and conflicting interests -- and must often content himself with patchwork solutions to the problems they generate. He must meet his quota, produce a profit, or face the company's equivalent of execution -- that is, termination.

The pragmatic approach can be considered a managerial strength insofar as it provides a way of coping with a multiplicity of problems; but it has severe limitations and can create its own problems. In the haste and willingness to compromise in finding solutions, he often fails to deal with the source of the problem and, by this technique, insures the problem's recurrence.

The importance of the managerial function is incontestable. The increasing complexity of the structures in our society, business and otherwise, has created a need for men who can handle a complicated mix of men, money, and time in achieving organizational goals. Aside from the basic prerequisite of making a profit for the organization, what contributions does the manager make to the organization and to society? Ultimately, it is his effort which determines whether a company will prosper. In a society such as ours, which depends primarily upon the wealth generated by the business sector, the status of the company influences, for better or worse, the status of the entire society.

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QA FOR SMALL PROGRAMS IN A LARGE INDUSTRY

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STRICT QUALITY CONTROL SUPPORTS BIG MILITARY AND SPACE PROJECTS

For a long time we have been in the habit of reacting to government contract requirements for quality control. The government quality specifications have gone through an evolution of ever-widening scope and increasing detail. In this context we have built up procedures that meet the requirements of MIL-I-45208A, MIL-Q-9858A, NHB 5300.4 (1B), and NHB 5300.4 (1C). Additionally, the government agencies have refined the requirements for individual projects or product areas, as with NASA's NHB 5300.4 (1D-1) for Space Shuttle and SAMSO STD 73-5B for Air Force space and missile programs.

We at McDonnell Douglas are deeply engaged in the development of highly complex product systems that demand intensive quality control. We regard the Military Services and NASA as primary market areas and must maintain the ability to meet their requirements. At the same time, we are busy with a wide variety of smaller projects. Some of these are commercially oriented. Some are for new agencies of the federal government, such as the Department of Energy (DOE).

R&D AND LIMITED PRODUCTION CALL FOR A CHANGE IN PACE

The big military and NASA projects that make the news do not appear overnight. Contractors who qualify to handle them have generally been through a long sequence of research and development activity that does not warrant the full measure of quality control. Recognizing this, the Department of Defense in recent years has put great official emphasis on tailoring quality requirements to the needs of the particular project at its particular stage of development. But it will take considerable time for these policies, such as in DOD Directives 4120.21 and 4155.1, to filter down into specific contracts. And, in the meantime, we are continuously engaged in a number of R and D programs in different stages of development.

What kind of quality program should the sophisticated Quality Assurance organization have for these smaller programs that we must handle concurrently with the large-scale projects. We cannot allow ourselves the luxury of the elaborate disciplines devised to get men on the moon. That is why we have had to devise methods with more latitude than is permitted by the procedures and formal documentation associated with large, complex projects.

Generally the small jobs are just as competitive as the big ones. That is to say, we must bid for them in competition with other firms, so we'd like to determine what control is essential and bid to provide that and no more. But we cannot economically indulge in a different QA system on each one of the scores of small R&D or commercial programs that are active at any one time. Such an approach multiplies management cost and causes confusion, lost motion, delay and waste in the work areas.

COMMON OBJECTIVES PROVIDE GUIDELINES FOR THE SMALL PROGRAM

At McDonnell Douglas Astronautics we have been learning to tailor our quality program to the level of control necessary for the smaller projects. Several examples of this are presented in this paper. The approach for different kinds of projects is based on some common objectives which can be summarized to provide guidelines as follows:

1. In a test or R&D effort, where the budget is always tight, sufficient discipline must be exercised that we run all the tests that are essential and that we test the right things the right way. We must make sure that we get what we ordered. We want to know what it is we've tested. The definitions must be good enough that someone else can repeat the tests and get the same results. Otherwise the tests

are not meaningful. Not every element of the design need be monitored, but characteristics that are significant in determining performance have to be pinned down. A first concern, then, is with how we'll define the product or work, how we'll order the work done, how we'll keep track of changes, and how we'll record the results.

2. In a limited production effort, for relatively simple products, we must exert sufficient discipline that we can be sure of meeting the customer's expectations. We must know that the design is adequate to meet our commitments. We want to know that the product is sufficiently like the design to give the customer what he reasonably expects -- no more and no less. The nature of the product, its intended purpose and the customer investment it represents will be major determinants in sizing the control program.
3. Finally, in any effort, we must exert enough discipline to optimize the cost to ourselves and to meet important schedules. The area where most latitude is available is in choosing the time, place, frequency and depth of inspection. Should we check at source, on receipt, during fabrication or processing, or just at the end of the line? Can we control effectively by sampling? Can we omit inspection entirely? The risks we can afford to take and those we can't will determine the answers to these questions. For example, elimination of in-process inspections may be a reasonable alternative if it can be done without significantly adding risk. Another alternative might be the delegation of certain verifications to Manufacturing.

Certain cares must be taken in tailoring a control system. It is important to recognize that the small programs benefit from a number of standard disciplines that are maintained for major space, missile and aircraft programs. Many of these can be applied selectively, but a few must remain standard. When we are looking for short cuts and setting up streamlined procedures, we must be careful that we don't inadvertently by-pass an essential control that might be taken for granted. First and most obvious of these is the calibration system. Any measurement made for the purpose of controlling, evaluating, or verifying what we do or make is wasted if we cannot trust it to some degree of accuracy. Another area to be safeguarded is the training and certification program for specialized skills. It's not only likely to yield specious results, but it may be downright dangerous to allow untrained personnel to perform certain inspections, tests or verifications.

Now let us look at a few examples of how the full blown quality program has been scaled down to the needs of individual smaller projects.

SMALL COUNTERPART TO A MAJOR PRODUCTION PROGRAM

CRYOANCHOR is the McDonnell Douglas trademark for an ingenious heat pipe used to stabilize the soil in arctic and subarctic regions. In such areas temperatures can range from -70°F or below in the dark of winter to as high as +100°F in the unending day of full summer. During the thaw, we find an active layer above the permafrost (meaning the ever-frozen subsoil). Power poles and pilings may be thrust upward and about in the unstable conditions of repeated thaw and refreezing during a change of seasons. The resulting effect on supported structures can be catastrophic. CRYOANCHORS are designed to remove heat from the frozen soil during the winter, further lowering its temperature and enlarging the frozen part of the unstable zone so that it will endure through the brief but intense summer heat. Over 120,000 CRYOANCHORS have been installed to stabilize pilings that support the Alaska pipeline as shown in Figure 1. These are heavy steel pipes containing liquid ammonia, each one topped by a press-fit aluminum radiator to dissipate heat.

Critical characteristics for top performance of CRYOANCHORS are the interior surface of the pipe, its texture and cleanliness, quantity and purity of the ammonia, and the soundness of welds and materials to secure the pipe against leakage for many years. The quality control program for a high-production operation at our Tulsa plant was carefully designed, with sampling plans for inspection and test precisely adjusted to assure a contracted reliability goal with known confidence. Verifications were made and recorded by full-time inspectors at each pre-planned inspection point.

In addition to the pipeline job, we have pursued a quite different market in supplying orders for lighter, more versatile, all-aluminum CRYOANCHORS to stabilize the soil under individual buildings and other structures. Runs are short, running from as few as six to perhaps 100 pieces for a single contract. The design is highly

flexible, being tailored to the particular application. For this reason, the job is done in the experimental shops at Huntington Beach, close to the sales and engineering headquarters. Typical of the output today is the installation near Fairbanks under a satellite-tracking Telemetry Station built for the European Space Research Organization. See Figure 2.

For the intermittent short runs of aluminum CRYOANCHORS, we took a different approach to quality control. Inspection and proofing of tools and processes were as strict as for the big production job at Tulsa. Two first articles were made and completely tested under the surveillance of a quality control manager. Thereafter the inspection function was wholly delegated to a senior mechanic in the experimental shops who is fully responsible for all operations, performing most of them himself with intermittent support in tasks that require more than one set of hands. Critical verifications are documented in the simplified work order that serves as a check list, and the senior mechanic makes all the entries as tasks are performed. A QA professional makes spot visits for surveillance and performs final review of the records when examining the completed lot for shipment. One specimen is then taken at random from each lot and functionally tested to verify performance.

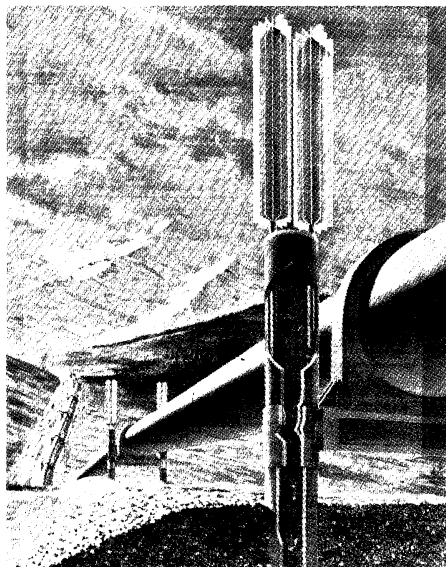


Figure 1. Cryoanchors for Alaska Pipeline

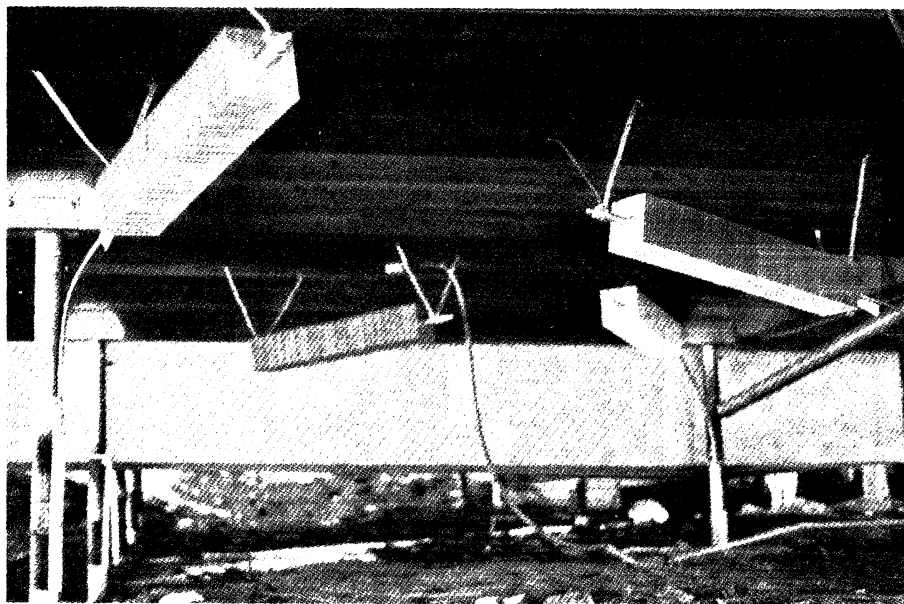


Figure 2. Cryoanchors for ESRO

The operation is small enough today that we do not wish to continue devoting the space and talent in the experimental shops to this diminutive but technically sound and proven bit of business. Because of its potential, however, intermittent production is performed while we actively seek to license manufacture of CRYOANCHORS by a capable firm that will develop the market.

DEVELOPMENT AND DELIVERY OF ONE OF A KIND

Optical sensors find many applications in space and weapon programs. In our space simulation laboratory, over the course of several R&D projects, we developed a unique capability to test such sensors in highly specialized environments. Concurrently, in laboratories and facilities at widespread points in the country, the ability was developed to generate other environments important for individual sensors. But our sensor tester was fixed at Huntington Beach. Because of the nature of the environments to be induced and because of the size of some environmental test facilities, one customer concluded that we should make a sensor tester that could be moved about the country.

Only one unit was to be built, and it had to be developed to meet difficult and exacting standards. Some of its characteristics include very high vacuum and extremely low temperature, simulating conditions in outer space. The optical characteristics require high precision with great flexibility to deal with a variety of types of optical sensors over a considerable range of the spectrum. For portability, the equipment had to be light and rugged, and it was determined that the vacuum tank should be designed to meet the ASME code for pressure vessels. Transducer, telemetry and electronic equipment to analyze results had to be redesigned and repackaged.

The quality program for such a one-of-a-kind product of high complexity was a considerable departure from conventional practice. Because only one unit was to be built, we were not overly concerned with the configuration of noncritical hardware. Proof of the pudding would be performance in development and checkout testing. For this reason, it was concluded that we could dispense with detail parts inspection and depend upon go-together as adequate for determining acceptability. If the parts fit, use them. If the parts don't fit, make the repair at the easiest point, which might be to modify the adjoining hardware. A master print of the assembly drawing was used to record such changes, and inspection was used only to verify that such inked corrections accurately described the hardware change. Only the welded vacuum chamber received detail inspection.

Functional testing was another matter. There was no prototype on which to establish performance capabilities and develop acceptance test procedures. The development article was the end-item. For this reason we selected a quality engineer to study and understand the performance goals, to verify that the planned test actually evaluated the required performance, and to monitor conduct of the test by our engineering laboratory team to see that the performance goals were met. It was on this basis that the quality engineer was able to certify that the end item met its performance requirements, although the requirements, like the hardware, went through an evolution during the course of the program.

What purpose did QA serve in such a program? Principally it was to keep order in a rapidly changing scene. Because of what QA did check, we knew when we were through that, sufficiently for the purpose, the hardware was like the marked drawing. We knew that the tests measured the performance characteristics correctly. And we knew that the actual performance was that represented to the customer.

LIMITED PRODUCTION IN A HIGH-TECHNOLOGY ITEM

A different problem is presented by short runs at rather long intervals of a high-performance hybrid microcircuit assembly for which reliability requirements are extremely challenging. The application is classified, but we can describe the end item as the size of a postage stamp, each with eight complex microcircuit chips mounted on a multilayer thick-film circuit board assembly and housed in a hermetically sealed package with thirty wire leads sealed in glass. Test requirements include functional electrical tests at two temperatures to the customer's specification at each of four points in the overall test cycle. A 100-hour burn-in is performed before capping the assembly and again after completing a series of environmental and leak tests adapted from MIL-STD-883. Chips are customer furnished and screened at source. Butterfly lead frames and the alumina substrates are purchased. We do the rest. See Figure 3.

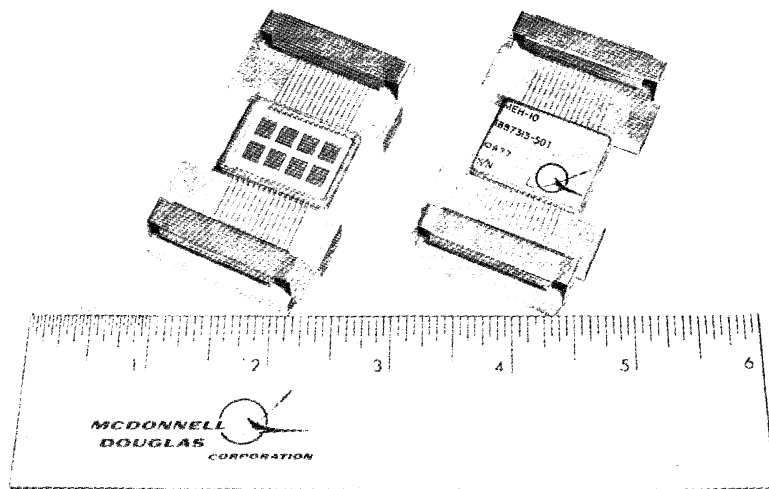


Figure 3. Hybrid Microcircuit Assembly Before and After Capping

For the initial order for 60 units, we performed a preplanned inspection of the complete manufacturing operation. This included examination of all detail steps. QA verified the preparation of screens and the screen printing of both conductors and dielectric on three substrate layers. This was followed by continuity and isolation testing. Then we verified, step by step, the installation of microcircuit chips, the wirebonding, and bonding of the substrate in the alloy box. Precap and final inspections completed the full-scale aerospace inspection approach.

For the second order we concluded that all the verifications just noted could be reduced to four examinations by having Manufacturing check off each operation as performed. QA inspection was limited to examination of the completed substrate, of the unlidded assembly before the first precap functional test, of the assembly just before capping, and of the fully tested end item before delivery.

The risk in this change was only with respect to manufacturing cost and schedule because of the general visibility in the unlidded box and because of the extensive performance testing that followed assembly. In all, nine QA verifications were eliminated. The acceptance rate in final precap inspection and in test has justified the change. A third run two years later has further confirmed the adequacy of control with the delegation approach.

Another change introduced for this product was to design a special-purpose rejection tag for use in testing as shown in Figure 4. This consisted of a pre-printed failure report permitting immediate entry of exactly what step in the test sequence failed. The shop work order shown in Figure 5 was designed to permit stopping at any point and recycling. These specialized forms are reproduced for the short runs required of this small but sophisticated piece of hardware. A single project-peculiar bulletin provides management authority for this departure from the formal material review system used for our major programs.

CONCLUSION

These are but a few examples of the flexible approach used in Quality Assurance to meet the challenge of diversification and of small R&D operations. The specialized procedures make optimum use of our standard practices, introducing variance only when it saves time and money and still provides control adequate to the purpose of the individual project. The modified systems work in parallel with major space, missile and aircraft projects that continue to get the full treatment. They work well because the activity is normally confined to a limited work area and performed by small teams who can be quickly instructed in special procedures for special cases.

HYBRID MICROCIRCUIT FAILURE REPORT
(for use when failure is indicated)

Part S/N _____ F/O# _____
 Procedure No. 1D19328-P200 _____ Chg. _____ Part Number _____
 Failure Date _____

Type of Functional Test (Check One Only)

		<u>Ambient</u>	<u>80°C</u>
Unsealed	-	Pre-Burn-In _____	_____
		Post - Burn-In _____	_____
Sealed	-	Pre-Burn-In _____	_____
		Post - Burn-In _____	_____
Post Gross Leak Ck		_____	_____
Final Test		_____	_____

1. Para. 7.2.26 TRA Failure (Circle Lamps that Light) 1 2 3 4 5 6 7 8
 2. Para. 7.2.38 TRA Failure (Circle Lamps that Light) 1 2 3 4 5 6 7 8
 3. Para. 7.3.15 IDD Current Failure
(Check if Answer is Yes) _____
 4. a. Para. 7.3.22 Input High Current Failure
(Check if Answer is Yes) _____
 - b. Para. 7.3.30-5 Adapter Terminal Failure
(Specify Terminals that Failed) _____
 5. a. Para. 7.3.26 Input Low Current Failure
(Check if Answer is Yes) _____
 - b. Para. 7.3.30-5 Adapter Terminal Failure
(Specify Terminals that Failed) _____
- Procedure No. 1D19328-P0600 _____ Chg _____
6. Para. 7.1.5.2 Fine Leak Test Failure
(Check if Yes) _____
- Procedure No. 1D19328-P0700 _____ Chg _____
7. Para. 7.0.16 Gross Leak Test Failure
(Check if Yes) _____
 8. Para. _____ Misc Failures Not Shown Above:
Describe Failure _____

Remarks:

Figure 4. Special Failure Report

FABRICATION ORDER
SPECIAL PURPOSE PAGE

THICK FILM ASSY
DATA LOGGING PAGE

SERIAL NO.		MODEL	PLANNING C/L	PART NO.			
		338001A		1B97313-			
SEQ #	DATA REQUIRED	STAMP	DATE	SEQ #	DATA REQUIRED	STAMP	DATE
030	RECORD SERIAL NUMBERS:			100	PRE-SEAL BURN-IN TEST		
	SUBSTRATE _____			(736)	TD19328-P0300 C/L _____		
	CASE _____			110	FUNCTIONAL TEST		
	BOND SUBSTRATE TO CASE			(736)	TD19328-P0200 C/L _____		
	EPOXY: LOT _____			120	PRE-SEAL CLEANING		
	DATE _____			(504)	VACUUM BAKE:		
	-3 BONDING				START COMP		
	CURE: START COMP				DATE _____		
	DATE _____				TIME _____		
	TIME _____				TEMP _____		
TEMP _____							
040	BOND CHIPS TO SUBSTRATE			130	INSPECT - QEC 0253		
	CHIP: LOT _____			(730)			
	DATE _____			140	SEAL PKG		
	EPOXY: LOT _____			(504)			
	DATE _____			150	THERMAL CYCLE TEST		
	CURE: START COMP			(736)	(MIL-STD-883)		
	DATE _____			160	ACCELERATION TEST		
	TIME _____			(736)	TD19328-P0500 C/L _____		
	TEMP _____			170	FINE LEAK TEST		
				(736)	TD19328-P0600 C/L _____		
050	GOLD WIRE			180	GROSS LEAK TEST		
060	WIRE BONDING			(736)	TD19328-P0700 C/L _____		
070	INSPECT - QEC 0252			190	GROSS LEAK CLEAN		
(730)				(504)			
080	TRIM AND CLEAN			200	FUNCTION TEST		
(504)	VACUUM BAKE:			(736)	TD19328-P0200 C/L _____		
	START COMP			210	POST-SEAL BURN-IN TEST		
	DATE _____			(736)	TD19328-P0300 C/L _____		
	TIME _____			220	FUNCTIONAL TEST		
	TEMP _____			(736)	TD19328-P0200 C/L _____		
090	FUNCTIONAL TEST			230	IDENTIFY		
(736)	TD19328-P0200 C/L _____			(504)			
				240	FINAL INSP - QEC 0254		
				(730)			
				UNIQUE SERIAL NO.			
24-646-09 (29 SEP 76)				PAGE			

Figure 5. Specialized Shop Work Order

LCS 310:10:439

COST OF QUALITY IN THE SERVICE INDUSTRIES

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INTRODUCTION

A review of the Quality Cost Literature based on the extensive index compiled by the ASQC Quality Costs Committee, revealed, that out of the 213 titles listed, 209 papers deal mainly or entirely with manufacturing applications, while the remaining four papers are related to the cost of clerical errors and purchased hardware quality, in the service industries.

This gross neglect of the topic of my title must have some well based reason. The search for this reason prompted me to conduct this exploratory study that intends to probe the viability of the Manufacturing Quality Costs Systems within the Service Industries.

The growing importance and size of the Service Industries should also be taken into consideration, particularly now, when in North America there are more people employed by Service Industries than by Manufacturing and Other Industries combined.

STUDY - STAGE 1

As a first step I held some informal discussions with Executives of services of a hospital, a Hotel and some Government Agencies. These discussions helped me to formulate the following observations.

Basic Quality Control terminology that is common in the Manufacturing Environment is not understood in the Service Industries. Questions that we often ask to evaluate Quality Systems may sound quite strange when put into the service environment.

Let us only mention a few:

"What is the Reporting Relationship of your Quality Manager within the Organization?"

"Do you have an up-to-date Quality Manual?"

"Do you have an active Quality Program?"

"Do you have a Quality Cost System?"

"How is your Reliability and Maintainability Program fit into the Quality Organizations?"

It would be erroneous to conclude at this point that the Service Industries examined are not adequately organized. Nevertheless, it is obvious that they are differently organized, and the single centralized Quality Function customary in the Manufacturing Industry titled as the Quality Control or Quality Assurance Manager has not emerged yet.

The design and control of quality in Hospitals, Hotels, Offices, etc... is inter-woven in their operating system, without one specific Executive being responsible for its co-ordination, and without clear definitions.

Discovery Number 1 - Management

"Service Industries are rarely structured for Vertical

Quality Organization."

The different aspects of quality are the responsibilities of several different Departments and Managers under most diverse titles without a central monitoring authority. This person is usually other than the Top Executive.

Some typical titles for Service Industry Quality Bosses are named here: Head Chef, Chief Housekeeper, Bell Captain, Head Nurse, Public Relations Director, Director of Pharmaceutical Services, Credit Manager, Catering Manager; It is easy to notice that these Managers are also responsible for the performance of the service itself.

Discovery Number 11 - Standards

"Standards of Services provided are not always defined from the Fitness for Use point of view. While the tolerances are very rigid or non existent, their enforcement and interpretation is very loose."

It is further complicated by Quality parameters such as timeliness, politeness and manners. Operating Procedures manuals are inventory and finance oriented. Acceptance or Rejection Criteria are rarely stated in writing.

Discovery Number 111 - Measurement of Conformance

"Measurement of Quality within the Service Industries, does not follow the traditions of manufacturing scoreboards."

The concept of failure is mostly a maintenance problem, and usually the total service provided only suffers a degradation rather than an outright failure.

For example, what is a "Failure" in a restaurant? When a customer fails to return a second time, dies of food poisoning, rejects the food, or the waiter drops it on the floor? - or a combination of several characteristics?

As service industries are heavily dependent on return business, the criticality of non catastrophic failures should be particularly emphasised.

At this stage of the study I had to return to the original title of the paper and draw an interim conclusion. For the Quality Professional, that emerged from the Manufacturing Industry, the immediate opportunities to apply his concept of Quality Costs is limited or remote.

It is common to try to apply a proven methodology in a new situation, only to realize that the differences outnumber the commonalities.

What is then the source of the incompatibility?

In my opinion the basic cause behind this observation stems from the fact that Quality Costs Systems are second generation Quality Control tools, that are successfully applied only after an already existing first generation Quality System is in place.

This observation may be considered as a personal opinion, and by no means indicates that the writer surrendered to the Quality Control Practitioners' arch enemy; -- "This will not work here" --.

To put this into a positive light, we should say the basic pre-requisites are not in place therefore the system will not function here.

To overcome this difficulty further studies are required.

STUDY - STAGE 2

The second stage of the study was then launched to explore alternate but complimentary avenues.

- a) A Systems Engineering Survey was conducted, with the objective of drawing up a map of all activities that have high content of Quality Work Elements. This survey also included the responsibilities and relevant available reporting and recording activities. As these studies were conducted for academic purposes, no actual action was taken on the findings, at least not for the time being.

The only benefits at this point were the better understanding of controllable variables.

- b) A study for discovery of opportunities for errors, material losses and customer dissatisfaction was then conducted. This study was mainly a review of the service-s provided and the activities required to perform the service-s.

The results were quite surprising. There were probably more opportunities for errors and loss of business, discovered than originally anticipated. A further disturbing fact came to light; the recognition that the order of magnitude is unknown and trends are not depicted.

The following observations are not intended to criticize the operations of the institution under study, only to highlight the elements of Quality Opportunities for control and improvement.

Hospital - Survey

Each functional director is responsible for the activity within its jurisdiction. There are no appointed individuals performing Inspection, Quality Control or Audit Functions and there is no date generated for analysis and corrective actions.

Quality losses or quality costs are generated within each functional jurisdiction, but none of them identifies them as such, however they include them in the budget as traditional facts of life;

- Medication delivery not in accordance with Doctor's instructions
- Medical instrumentation not fully serviceable
- Pilferage and breakage of equipment
- Availability of Medical and Housekeeping staff not co-ordinated with patient population
- Non availability of accommodation when patients are admitted
- Errors in Quantities and Qualities of Food supplies
- Lack of synchronization of housekeeping with patient care
- Building and Maintenance failures, reliability and maintainability problems
- Record errors, storage and retrieval
- Clerical errors in accounts receivables and accounts payable
- Unnecessary laboratory work, due to administrative and identification errors
- Liability claims
- Moral and attitude problems of the employees

The need for scorekeeping on degree of compliance with standards is obvious. If we had the; who should do what, when and how, and had someone record, the deviations and losses within the different functional directorates (overlapping geography) we could easily add the dollar values. The operating instructions are more implied than specified.

At present, instead of Quality Cost Reduction programs, most Service Institutes are budgeting for traditional "losses" as part of the Historical Operating Cost. Maybe we as taxpaying citizens should challenge the "Unknown Losses" because they may not be

"Unavoidable Losses". It is not uncommon to hear budgeting for 10% food spoilage, 5% linen pilferage and a very extensive list of medical supply disposal due to expired shelf life.

The question of avoidable losses and the philosophy of "planning for errors" is a serious problem to contend with.

Hotel - Survey

The similarities in organization and sources of unqualities between a Hospital and a Hotel were striking.

The concepts for Quality Control are almost identical;

- Services delivered not in accordance with customers request or expectations
- Reservation system errors
- Availability of staff not synchronized with public needs
- Errors in quantities and qualities of food supplies
- Failures in Electro/Mechanical equipment and long response time for correction
- Timing of housekeeping in conflict with guests' comfort
- Clerical errors in billing and accounts payable
- Unnecessary services offered and rendered
- Pilferage by staff and guests
- Liability claims
- Moral and attitude problems of the employees

Due to the fact that the quality losses are directly effecting the profitability of the operation, we may find an earlier breakthrough in this field. Nevertheless, the groundwork is still missing.

SUMMARY

An attempt to apply Quality Cost Systems to the Service Industries at the present time and in state of the art would be rather premature.

To hang price tags on items that are not fully defined for the majority of Service Industries, and to attempt to transplant manufacturing titles and labels with different meanings is an invitation for failure or at least for confusion.

It seems that an enormous opportunity and probably an equally large need exists to develop the First Generation Quality Systems for the Service Industries.

It will require the identification and recognition of the universal aspects of quality within the different Service Industries, minimizing the specifics, emphasizing the commonalities.

The experiences learned by the Quality Practitioners in the Manufacturing Industries could become very useful, we must always bear in mind, that Management and People Problems are more difficult to deal with than the technical problems. Therefore the common ground at least at this point is in existence.

When this First Generation Quality System Development will reach its maturity, the methodology of Quality Costs Systems will become timely. It may require major changes from the present manufacturing format to the future Service Industry model.

As executives of all Industries are most familiar with dollar and cent reports, the arrival of the Quality Cost System will become beneficial and well received but not before the quality system itself is established and well understood.

The concepts of Total Quality Control may very well be the approach but will have to be re-developed from first principles

as a joint effort of the Quality Professional and the expert of the specific Service Industry involved.

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THE ROLE OF QUALITY IN BANKING

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To effectively demonstrate the role of Quality as it relates to Banking, we must first analyze our objectives.

In Banking, we have a two fold objective--customer satisfaction and the availability of funds.

To attain these goal objectives, we must design and implement programs and measurements that will permit us to fine tune the system for maximum efficiency.

First, we must through statistical applications determine the bandwidth of performance for our clerical staff, as well as our hardware and the product we are processing.

Reductions in defectives (rejects) will give us increased availability of funds and customer satisfaction.

To establish a Quality Assurance and Quality Control System to attain these objectives is, to say the least, an extremely difficult task, but we at Chemical Bank have made tremendous progress in this direction and we would like to share our story with each of you.

Our first recommendation is a Pre-delivery Sampling Program of all customer checks, prior to customer delivery. This requires a cooperative effort by the Purchasing Department, account officers, and an active role by the branch managers. A sampling based on an AQL of 0.4% will give results of a very substantial payback.

This program of on-line testing of checks will verify compliance with ABA specifications pertaining to MICR (Magnetic Ink Character Recognition), routing transit number and account number verification. A feedback mechanism is then established with Purchasing and the check printers developing measurement standards on submittals and a corrective action program that will enhance production efficiencies on the part of the check printers and improve the quality of the checks.

Design is an important ingredient relative to the product and has a great impact on over-the-counter deposit tickets, Debit memos and credit memos--from the standpoint of size, paper weight, and legibility of information--are an important ingredient to accomplish the task of improved quality in this area. It is important for Quality Control to be an integral part of the design review and sign-off process.

As in every production process our human resources become our most important element for success or failure in the attainment of our goal objectives.

We at ChemBank have instituted Quality Sampling Programs to monitor the performance of our operators by designing forms and itemizing possible errors that an operator can make; we then establish a random table selection for operator sampling. Weekly charts are submitted and by designing an error/operator matrix, error patterns can be analyzed for immediate corrective action. This

feedback of data including weekly process average and process capability reporting, determines which operators are to be monitored for defined error categories.

Last, but most significant, is the monitoring of hardware performance through software applications and statistical applications; goal objectives are determined for encoder and sorter performance.

No longer is a subjective judgement of projected performance accepted. All "Super Goal" objectives are defined through sound statistical applications.

Once these programs are in place, we can validate our sampling programs to our actual performance, thereby tailoring our operating characteristic curves to tighten or reduce our sampling based upon our actual performance.

By developing a "Monthly Performance Report on Quality Indicators," we can obtain an analysis of encoder performance, sorter performance, and measurements of product lines, i.e., Incoming, Mail, P & R, Total Volume, and "On-Us" items.

As a follow-up, measurements are made on errors impacting customer statements, determining cause and correction prior to statement rendering.

This is followed by postal card surveys to customers on a random basis for any statement discrepancies or other comments; as customer satisfaction is our prime objective.

LCS 310:20:760

MICROCOMPUTERS AND SOFTWARE QUALITY CONTROL

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INTRODUCTION

Microprocessors - - you can hold a dozen in one hand, yet each may have more raw computing power than the largest computer which existed in 1949. Such is the rate of change in the computer industry. The microprocessor was born in 1971 when an Intel engineer, M. E. Hoff, Jr., developed an integrated circuit (IC) chip for a Japanese calculator company, Busicom. Busicom wanted a family of business calculator products to meet various market requirements. Hoff felt that to custom design a whole series of chips would not be very cost-effective, and proposed an elegant solution: a central processing unit (CPU) chip would be designed to interact with a read-only memory (RAM) chip, to form a stored-program computer. Then each specific calculator would be implemented by a particular program stored in ROM.

The job of customizing calculators was thus transformed from building different hardware to writing different software, a major intellectual breakthrough. The CPU Hoff designed was named the Intel 4004. It used a 4 bit data structure and p-channel metal oxide semiconductor (PMOS) technology. Although the 4004 was rather slow, and did not originally attract any attention in the computer industry, it started a revolution the end of which is nowhere in sight. Intel followed it with the 4040, the 8008 (using 8 bits), the 8080 (using n-channel technology or NMOS), the 8080A (currently an industry standard) the 8048, and the 8085. Each successive chip tended to run faster, provide more functions, use less power, and cost less money than its predecessor.

Soon competition appeared and the industry was born. Motorola, Rockwell, Texas Instruments, National Semiconductor, and other large firms entered the microprocessor market. Small companies such as MOS Technology, MOSTEK and Zilog developed new chip designs and provided second sources for established ones. Today about 60 companies are manufacturing microprocessors, and thousands of companies are building them into other products.

MICROCOMPUTER RELATED PRODUCTS

Since there are several microcomputer-related products which are often confused, some definitions are in order. With the passage of time, the more innovative manufacturers of each product type have incorporated some of the better features of other types into their products, so the distinctions will become more blurred as the industry evolves. These definitions and examples represent each type as originally conceived.

Microprocessors

A microprocessor is a large scale integrated (LSI) digital processing circuit on a single silicon chip. It contains registers, data paths, and control logic which permits the execution of programs. The machine language instruction set is completely defined by the control logic. Prices may range from \$3.00 to \$50.00. The chip may be mounted on a dual-inline package (DIP) providing the gourmet computerist with chip-on-DIP. A microprocessor does not include any access or display methods such as keyboard or light-emitting-diodes (LEDs), or nor does it include any memory for storing programs or data. Microprocessors are built into many products besides computers, such as machine tools, auto ignitions, calculators, home appliances, and games. Representative products are the 8080A, the Motorola 6800, the Zilog Z-80, and Texas Instruments 990.

Microcomputers

A microcomputer is a module which consists of a microprocessor, some memory, normally both RAM and ROM, input-output interface circuits, a clock, and other logic such as buffers and drivers. The earlier microcomputers placed each of these functions on a separate chip, then hooked them together on one or more printed circuit boards. However, new microcomputers such as the Intel 8048 include most or all functions on one chip, giving rise to the expression, "computer on a chip." Some popular microcomputers are the Intel SBC80/10, the Altair 8800, the Heathkit H-11, and National Semiconductor's SC/MP. Prices run between \$100 and \$1200.

Microcomputer Systems

A microcomputer system is created by attaching various input-output and auxiliary storage devices to a microcomputer. There are many subgroups in this product classification, with new ones appearing all the time. One class is the microcomputer development system (MDS) which can be used to develop new microcomputer systems as well as write programs in assembly language and high-level language. A leading example is Intel's INTELLEC system, which retails for about \$20,000. In contrast is the home computer, which includes a keyboard, CRT, and cassette tape unit. The two most popular home computers are presently the Commodore PET 2001 and the Radio Shack TRS-80. Both were introduced in late 1977, retail for \$600, and include a BASIC language processor in ROM. In between the two above extremes are small business systems, laboratory data systems, and hobbyist systems. By thumbing through a recent issue of Byte or Mini-Micro Systems one can see many examples. Some brand names include Polymorphic, IMSAI, Processor Technology, Apple, Heath and Digital Group.

Minicomputers

These have a much longer heritage than microcomputers, having first burst upon the scene in the early '60's. The original distinctions were along the lines of price (minis about 5 times as expensive), speed (minis operating at about three times as fast) and word size (typical minis were 16 bits, vs. 8 bits for the micros). The company largely responsible for the minicomputer industry is Digital Equipment Corporation, and its most successful products have been the PDP-8 and the PDP-11. The latter design was converted into integrated circuit technology and renamed the LSI-11, which then also became the H-11 under a licensing agreement with Heath. This switch left the architecture unchanged, but reduced the price, speed, power requirements, and volume. So is the H-11 a minicomputer or a microcomputer? Other leading minicomputer manufacturers are Data General, Computer Automation, Hewlett-Packard, and Wang.

Programmable Pocket Calculators

These are sometimes confused with microcomputers. This is understandable, since there is a microprocessor in every programmable calculator. The important distinction is that the capabilities of the calculator are restricted to numerical calculations using a sealed control program; whereas a true computer can be loaded with any type program and data the user sees fit. The programmable calculators, though less flexible, are much easier to use than microcomputers for straight numerical computations. In fact, numerical computations are distinctly difficult for microcomputers. Either a separate chip or special software is required to do this. The Hewlett-Packard HP-65 was the first programmable pocket calculator. It sold for \$800.00. A currently popular programmable calculator is the SR-59, sold by Texas Instruments for about \$300.00. This calculator has a printer and magnetic card storage. It also has program libraries stored in removable memory modules, which provide for extremely convenient program execution.

MICROCOMPUTER SOFTWARE

When microcomputers first became available, software development facilities did not exist. System engineers were forced to translate programs into machine code by hand and then toggle them into the machine through the front panel. This state of affairs has now improved, but the facilities for debugging and developing microcomputer programs are still far more primitive than those available to large computers.

Classes of Software

For purposes of this discussion, microcomputer software is divided into three classes: (1) systems, (2) developmental, and (3) applications. Systems software, is that which helps a fully developed system to provide the service for which it was originally acquired. The operating system is the prime example. Developmental software includes language processors to create software, such as assemblers, BASIC, PASCAL, PL/M and muPro; and test software to validate programs, such as the National Bureau of Standards test series (1). Applications software constitutes all the programs which perform the final end result of the computer. Text editors, mathematical routines, computer game programs, and machine control software are examples of the wide spectrum of applications programs. There are currently many thousands of such application programs in existence, and more are being created every day. They are being sold, licensed, exchanged in User Groups, and given away. Little is known of their quality or reliability!

How Much Software Do Micros Require?

Depending on the use planned for the computer, a whole lot or very little software might be required. Computers which are imbedded into products will normally have one program written to perform the desired function, which is then permanently stored into a read only memory (ROM). (Such a program is often called firmware, gray area between software and hardware.) On the other hand, a general purpose machine such as the MDS or a small business system, must use a wide variety of software to justify its purchase. Various language processors and application programs may be stored on floppy disks or cassette tapes. Depending on the resources of the organization, the programmer, developer, and user of microcomputer systems may have to accept rather primitive software for testing and debugging. This is one major challenge for microcomputer software quality control. Large system programmers are used to elaborate diagnostics, tracebacks, and dumps. These software aids have evolved over the years and are in large measure dependent on the large memories available. No such sophisticated developmental software exists (as yet) for the microcomputer programmer. This means a much higher level of training, planning, self-disciplined step-by-step check-out by the programmer is required. Quality control people can provide a real service to the profession and the industry by participating in such a program.

RELIABILITY OF MICROCOMPUTER SOFTWARE

A computer user supposedly asked the manufacturer's representative why he had so much more trouble getting the software to work than the hardware. "Why are your engineers smarter than your programmers? Why don't you test your software as well as your hardware" (2). The answer is that software is not only inherently more complex, it is fundamentally different from hardware. A purely intellectual product, its success or failure depends on many external factors which are not easily controlled or tested.

Software Errors

Myers (2) defines a software error as an incident where the software does not do what the user reasonably expects it to. This definition puts the burden on the programmer to understand what the user may reasonably expect; a software error is not a property solely of the software. Careful definitions of requirements and program restrictions are essential.

Cost of Software Errors

Foster (3) estimated that software costs from ten to three hundred dollars per instruction. To most programmers this seems unreasonable high, but when one recognizes the total spectrum of activity which must be charged to each instruction it is not quite so unreasonable. For instance, Myers (2) claims that program coding accounts for only about 10% of the total cost of software, the other 90% being in design, testing, and maintenance.

If a statement costs from \$10.00 to \$300.00, what does a "bug" or software error cost? Like most defects, it depends on where the bug occurs. A missing comma in a FORTRAN program in an early space launch caused the destruction of a multimillion dollar rocket. This is a spectacular but exceptional case. As another example, if a product is manufactured with a bug which must be later removed by replacing the ROM,

the cost is very possibly going to be in the order of \$100.00 for parts and labor on each copy of the product which has reached the field. If several months have passed since product marketing, over 1000 copies would probably exist. So one bug in the wrong place could easily cost over \$100,000. And this would far exceed the total development cost in most cases. The mass production of microcomputers creates quality cost problems never encountered in the larger systems. Microcomputer software reliability is important!

ACHIEVING SOFTWARE RELIABILITY

Reliability is one of several conflicting objectives of software development. Cost, delivery time, and function are also important parameters. The ideal software which is extremely powerful, highly reliable, low in cost, and quickly produced, clearly does not exist. Thus tradeoffs must be made, based on perceptions of market requirements and the organization's capabilities, just as J. M. Juran has explained to us for many years. To summarize much that has been published in symposia, proceedings, books, and technical journals, we offer the following fundamentals:

1. Provide tools and skills appropriate to the task. A wide array of development systems, software test programs, software analysis systems, etc., are available. Numerous short courses are being offered on structured programming and software engineering. There will always be a shortage of highly qualified programmers who write error free code the first time!
2. Apply sound program design techniques. A careful requirements analysis, unambiguous specifications, appropriate documentation, and structured programming are examples.
3. Test software thoroughly. The importance of adequate testing can hardly be overemphasized, and is discussed in further detail below.
4. Control change once the program leaves the hands of the original programmer. Foster (3) Provides many details regarding change controls and documentation.

Software Testing

The Association for Computing Machinery (ACM) sponsored a program testing symposium in 1973 (4) which provided the basis for the following definitions. Testing is the process of program execution with the goal of finding errors. Verification is testing in a simulated environment. Validation is testing in a real environment. Other important terms are module testing, integration testing, system testing, acceptance testing, and installation testing. These terms have obvious analogues in traditional manufacturing quality control.

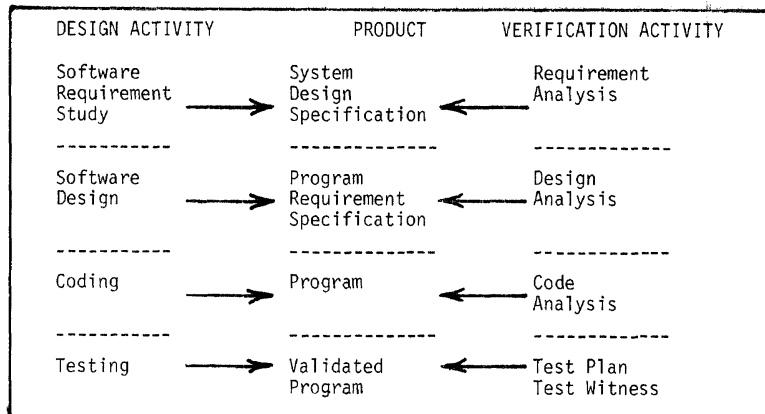


TABLE I
Relationship Between Development
And Verification of Software

It is rather generally agreed that no programmer should be expected to test his own program. There appear to be two fundamentally opposing philosophies as to how to involve others in the testing. One is the structured walk-through of the Chief Programmer Team, where colleagues of the programmer study the program carefully and attempt to help the programmer improve it. The other is the independent verification process managed by a separate organizational group. A summary of the development and test process is given in Table I, which was adapted from (5).

A study of Table I shows that for each product created in the software development process, one task is performed by the design group and an analogous one is performed by the verification group. This type of approach is probably not common for micro software.

More common is the approach taken by Insite, the Intel Users' Program Library. Insite is one of many software libraries growing rapidly to support the microcomputer movement. They are being developed both by computer manufacturers and by independent software houses. They tend to emphasize application programs. Programs submitted to Insite will support all computers based upon the 8080, 8085, and 8048, and many of them would with minor modifications support computers based on the Z-80. There are hundreds of programs, in fields varying from engineering analysis to statistics to games and peripheral control. Members are encouraged to submit programs, which when accepted earn a year's free membership, or five free paper tapes, or one free program diskette. Any of these options is worth approximately \$10.

Now it is obvious that for \$10 in service a submitter does not have an incentive to do a great deal of program testing. Insite does not in any way guarantee the programs, or attempt to test them. It does require that in addition to source listing, source code on paper tape or diskette, and the usual factual details, that the programmer provide "a test program which assures the validity of the contributed program." The exact nature of the test program is not specified beyond the quoted phrase. One would assume that Insite expects the programmer to choose some representative data, run the program with this data, and submit the successful run as the test program. What kind of validation is that? What is the probability that the software obtained will perform in the way the user reasonable expects it to? Neither Insite nor any of the other software libraries provide a quantitative answer to that question, but the reader can guess that the probability is low.

It is not intended to single out Intel for criticism. In fact, Intel is one of the most responsible companies in the microcomputer business, and the price being paid for the software cannot support a great deal of testing. Nevertheless, many unsophisticated buyers of microcomputer software are buying, and will continue to be buying, software with bugs in it. When these bugs spring forth, many of the users will be completely baffled as to whether they have a user error, a software. Many will lack both the skills and the equipment to make the determination.

Some sort of national effort is needed to monitor the quality of microcomputer software, and to provide objective standards against which each source of microcomputer software can be judged. In other consumer items there are organizations like Consumer's Union. Where insurance hazards exist, there is the Underwriter's Laboratory. Who will perform this service for the microcomputer software? The National Bureau of Standards? The Associate for Computing Machinery? The American Society for Quality Control?

LCS 640:70:000

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A PROGRAM FOR SOFTWARE QUALITY ASSURANCE

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INTRODUCTION

At TRW Defense and Space Systems Group the need for a division-wide organization to assist software management became quite apparent during the late 1960's. Like most other software vendors, TRW was concerned about the frequent cost overruns and schedule slippages in its software projects, and decided to develop methods to turn this trend around. As part of that decision, it established its first software quality assurance staff in 1969. Though small in number, this group was staffed by very strong management and technical people. The first few months were spent doing what many new organizations do: defining their job, hiring their staff, and marketing their services. Much of the early effort was spent writing QA policies, plans, and procedures, developing automated QA tools, and participating on proposal teams. This effort paid-off handsomely as the software subcontract for the Site Defense Program (later known as the BMD Systems Technology Program) was proposed in 1971 and won in 1972 with a very heavy (40 man year) dedicated quality assurance role.

Managers in other projects soon saw that the software quality assurance function could solve many of their problems, and slowly they began to employ QA personnel both in a full time project-dedicated capacity, and on an as needed basis. As software quality assurance became more active in a wider variety of projects and environments, the tasks it performed became better defined and more standardized among the projects in which they were employed. The remainder of this paper describes more fully the purpose, functions, organization, benefits, and lessons learned with regard to the current implementation of software QA at TRW.

PURPOSE

The purpose of software quality assurance is clearly to assure the quality of software products. However, the words "assure" and "quality" can be interpreted in several ways, so it is important to begin with a discussion of the role of quality assurance (QA). The purpose of software QA as stated in MIL-S-52779 (Software QA Program Requirements) is "... to assure that software delivered under the contract complies with the requirements of the contract." The problem with this definition is that if a contract specifies poor software quality (inadequate documentation, poor standards, insufficient testing, etc.) the software QA program will assure that you get poor quality software. An expanded definition of the purpose of software quality assurance is:

To assure sufficient planning and control to affect the development of software products which meet the specified and intended requirements in the areas of:

- Accountability
- Usability
- Testability
- Reliability
- Maintainability

FUNCTIONS

The detailed functions of software QA vary from one project to another, but generally can be grouped into 8 functions:

1. Initial quality planning
2. Development of software standards and procedures
3. Development of quality assurance tools
4. Conduct of QA reviews and audits
5. Inspection and surveillance of formal tests
6. Configuration verifications

7. Management of the discrepancy reporting system
8. Retention of QA records.

Initial Quality Planning

Experience has shown that like other project functions, successful implementation of the QA program depends heavily on QA planning during the early phases of the software development life cycle. This task is accomplished by a complete review of early project documentation (e.g., the Contract Statement of Work, System Specifications, Project Plan, etc.) The review culminates in the preparation of a QA Plan which contains the quality assurance functions, tasks, responsibilities, and identifies the QA tools needed to assure sufficient software quality with regard to accountability, testability, usability, maintainability, and reliability. The QA plan is then reviewed by other project organizations, and approved by the program manager and customer. After QA Plan approval, task assignments are made to carry out QA functions, however, these assignments are usually based on level-of-effort and must remain flexible to adapt to:

- The needs of the current phase in the development life cycle
- Shifts in attention-needing areas (e.g., technical problems)
- Unexpected demands placed on QA by the project manager

After QA Plan approval, QA policies and procedures are written which describe the methods and procedures to be used in implementing the quality assurance requirements as defined in the:

- System Specification
- Contract Statement of Work
- Project Plan
- QA Plan

A sample table of contents for QA policies and their associated procedures is shown in Table 1.

Table 1. Sample QA Policies and Procedures Titles

1. <u>QA Management</u>	4. <u>Software Turnover</u>
2. <u>Reviews and Audits</u>	4.1 Software Installation
2.1 Specification Review	5. <u>Discrepancy Reporting</u>
2.2 QA Audits	5.1 Discrepancy Analysis
2.3 Standards Compliance	5.2 Discrepancy Surveillance
2.4 Unit Development Audits	5.3 Deviations and Waivers
2.5 Test Plan and Procedure Review	6. <u>Configuration Verification</u>
3. <u>Inspection and Test Surveillance</u>	6.1 Configuration Verification
3.1 Unit Test	7. <u>Quality Assurance Records</u>
3.2 Integration Test	7.1 Description of QA Records
3.3 Validation Test	7.2 Discrepancy Report File Maintenance
3.4 Test Review Board Operations	

The payoffs of continually planning, setting priorities, and maintaining project-wide visibility cannot be underestimated. QA effectiveness is directly proportional to the visibility that QA has into the project and the organization's involvement in the planning process.

Development of Software Standards

The purpose of software standards is to improve the maintainability and readability of the software product. At TRW, a comprehensive and detailed software standards program has been successfully instituted to achieve this purpose. This success can be largely attributed to two factors:

1. Software standards are not dictated from the executive offices, the project offices, or from Quality Assurance, but are developed out of close communication among the design and development, test, QA, and project offices.

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2. A tool has been provided to automatically check the software against most of the standards. This allows programmers to audit themselves so that there are no surprises at turnover time.

Waivers and deviations complement the standards by providing mechanisms for handling allowable non-conformances with the standards. They provide permanent or temporary relief, respectively, from standards compliance due to, for example, technical difficulties, inefficiencies, or schedule impact, and must be approved by the QA and project managers.

Development of QA Tools

The short history of software development is laden with excuses for poor performance. True, many of the excuses are due to people problems, but many also are due to technical problems. While tools can't solve the people problems (unless the tool replaces the people), they have been used with great success to solve many problems in technical areas. For example, tools perform many functions in the areas of file management, data base generation, code verification, and test assistance. Generally software tools should perform tasks that are more cost effective and accurate if done automatically than if done manually. This includes tasks that are often tedious, menial, boring, difficult, error prone, repetitive, and costly. Therefore it is not surprising that quality assurance groups make heavy use of software tools.

QA tools are essential to the successful implementation of a software QA program because they provide a cost effective method for accurately evaluating large software products in a short period of time. At TRW, software QA personnel have developed numerous tools to assist in their tasks, but have found the below sample perhaps the most highly successful.

Product Assurance Confidence Evaluator (PACE) -- PACE is a unique tool to aid program developers and testers in the planning, execution, and evaluation of both unit level and program level tests. The object of PACE is to quantitatively assess how thoroughly and rigorously a program has been tested. PACE is the tool that is used to assure that every instruction and branch be subjected to an execution test.

Fortran Code Auditor -- The Fortran Code Auditor is the first known automatic standards auditor in the software industry. It was developed in 1973 to audit eighteen software standards, and has increased today to thirty-four software standards. Code Auditor is heavily used by both programmers and quality assurance engineers. It has been a valuable tool because it permits the enforcement of a comprehensive set of coding standards which reduces the number of software errors, improves execution efficiency, and improves readability and maintainability.

The benefit of the Fortran Code Auditors is that it not only automatically audits a large amount of code in a matter of seconds, but provides a means for programmers to audit themselves prior to turnover.

Structured Programming Auditor (STRUCT) -- STRUCT is the QA tool used to verify compliance with the structured programming standard. It is executed after PACE, as it uses the Segment Transfer Table as output by PACE to convert each source routine into its directed graph representation. STRUCT then performs a flowgraph reduction algorithm on the Segment Transfer Table to determine if each routine is structured according to the six following constructs: sequence, if-then-else, do-while, do-until, case, escape-from-loop.

Units Consistency Analysis (UCA) -- The UCA Program scans Fortran source code and its associated data base (for access to variable units definition) and symbolically interprets the equations referencing the variables to assure that the units are correct and consistent within the assignment statements. For example, in the assignment statement

$$C = A * B$$

if variables A and B were defined to be in units of feet, variable C ought to be defined in units of square feet or a diagnostic would be printed.

Conduct of QA Reviews and Audits

The most important task for QA is to ensure that the QA policies, procedures, and software standards developed and identified in the appropriate documents are carried out. To this end, informal and formal QA reviews and audits are conducted incrementally on software products.

In the context in which they are employed at TRW, reviews are QA critiques performed against documents, whereas audits are QA critiques performed against processes, often scheduled near a milestone event in that process. The criteria against which documents are reviewed are:

- Adherence to format and pagination standards
- Clarity of objectives
- Technical content
- Interdocument consistency
- Traceability to higher level specifications

QA audits usually include document reviews, and in general perform four functions:

- They assess compliance of source code and documentation to software standards and procedures;
- They assure traceability of requirements
- They determine the satisfaction of system requirements during system test and acceptance phase;
- They assess test sufficiency.

The following audits may be performed on software projects:

Software Requirements Audit — This audit is conducted prior to the system design review and includes the review of the software specifications, projects plan, and test specifications. QA reviews these documents to determine whether:

1. Software requirements are traceable to system requirements
2. The planned testing will assure satisfaction of software requirements.

Interface Verification Audit — The interface requirements, design, and programming specifications are audited as early as possible to identify and correct potential interface problems. The process of auditing an interface specification is similar to the above. QA personnel may also participate in a weekly meeting of the interface control working group.

Preliminary and Detailed Design Audits — These audits are conducted prior to PDR and CDR, respectively, and are concerned with the format and content of the design documentation and test plans. Results of the findings are discussed during the PDR and CDR, respectively.

Incremental Development Audit — The incremental development audit approach involves the conduct of periodic audits during the code and unit test phase. This allows the developers time to implement corrective actions in their Unit Development Folders (internal programmer documentation) and code without seriously affecting cost and schedule performance. The use of checklists facilitates the audit, as it standardizes the audit process and lets the developers know ahead of time what to expect. Incremental development audits include:

1. Verifying that changes to requirements, design, and interface definitions are maintained and updated;
2. Verifying that any applicable design or code walk-throughs were properly held;
3. Audit of source code for standards compliance;
4. Assessment of test sufficiency or thoroughness of unit testing;
5. Adequacy of configuration identification and control.

Pre-Turnover Audit — Prior to the turnover (delivery) of the software to the test team, a pre-turnover audit is conducted to assess the adequacy of unit testing. QA evaluates the total software product being turned over in terms of:

- Actual versus expected test output
- Change control status verification of code
- Completeness, content, and organization of Unit Development Folders
- Code compliance to applicable software standards
- Data base control

- Test sufficiency
- Discrepancy report status

This audit must be well planned and executed efficiently in order to obviate schedule impacts. Adequate time should be allotted to negotiate corrective action items and correct deficiencies in the software documentation prior to deliver to the test team. This audit is complete when QA certifies the condition of the software, and the test manager accepts the turnover package.

Test Audit — Software test audits are conducted at the completion of each test phase. Their purpose is to:

- Assure that sufficient software configuration management procedures are being followed;
- Assure that test specifications used by the test group are the current approved versions;
- Assure that test reports identify proper test procedures and software configuration, specify the test analysis, and if any deficiencies or deviations were noted, how they were explained and accounted for;
- Verify that test procedures provide a step-by-step rationale for conducting a test, and that test results comply with acceptance criteria specified in the test procedure;
- Verify that test data packages comply with approved formats. A test data package is a stand-alone set of documents which contain test procedures, test reports, discrepancy reports and test results, and facilitate an independent review of this package by the customer;
- Verify compliance by the test team with stated management procedures for change control, discrepancy reporting, test reporting, etc.

An audit during the preturnover period should be conducted at a key point during the testing phase to allow time for corrective actions prior to software product demonstration to the customer. In addition, this audit should not be confused with the inspection and test surveillance function described in the next section. The inspection and test surveillance function is a part of the daily QA involvement with the test activities and differs from an audit, which has contractual connotations and provides definite corrective actions and direction to the test activities.

At the conclusion of the final test phase, the software QA organization certifies that the computer programs satisfy their specified contractual requirements. This certification is done prior to the turnover of the software to the customer/user organization.

Inspection and Surveillance of Formal Tests

Inspection and test surveillance is an on-site activity performed by QA personnel during program testing. Specific tasks include:

- Monitor all tests to ensure that actual tests performed are as specified in documented test procedures. This is accomplished via QA signoff on the test execution report.
- Assure that all potential discrepancies are recorded in the approved manner.
- Compare the configurations of hardware/software components utilized in the test against the configuration identified in the test procedure.
- Certify that analysis of the test output is correct, the test satisfies its intended requirements and acceptance criteria, and that the test data package is complete.
- Assure that master copies of test procedures, test results and test reports are maintained and available from a centralized records center.

Verification of Configurations

New versions of programs are usually released after formal configuration control procedures have been applied. An important QA function is to perform configuration tests on the controlled master libraries of each version to assure that no inadvertent or unauthorized code changes have been made. One method is the three-step method currently being used to carry out this function: 1) isolate the approved modifications, 2) delete those modifications from the new master file and replace any removed code (this is done automatically by a library management system), and 3) compare the old file and the rearranged new file. (An operating system utility does this most efficiently). They should compare identically. Any discrepancy should be

brought to the immediate attention of the configuration control manager for corrective action. A letter certifying the authenticity of the new file may accompany the new release notice. Other configuration verifications may be incoming and outgoing shipment packages where QA personnel inspect the product packages to assure that the contents are as specified.

Management of the Discrepancy Reporting System

An important management control mechanism is the accurate recording, tracking, and reporting of all real and perceived project discrepancies. The Quality Assurance organization with its independent, project wide visibility is often the prime candidate for this job. As discrepancy reports (DRs) are written, a copy should be given to the QA office for logging. As is often the case, the original DR gets sent to a central management review body who decide whether the DR should be rejected, deferred, or accepted, and if so, who should fix it. By making QA a member of this body, they can track each DR and report its status at any point in time. Periodic error trend analyses can then be made which report, for example:

- The error rate for various programs
- The number of open DRs
- The relative frequency of DRs in various defect categories
- The average time to close various problems

Retention of QA Records

The previous seven QA functions often create voluminous paper, much of it contractual in nature. To properly retain and control this paper a repository with formal procedures needs to be established early in the project life cycle. On small projects this may involve only a secretary with a locked file cabinet, while on larger projects QA may make use of a centralized data management center. In the quality planning stage during proposal or contract definition, the appropriate QA records should be defined and resources budgeted for this control. These records may include:

- QA Plans
- QA Procedures
- Design Problem Reports
- Discrepancy Reports
- QA Audits and Reviews
- Test Data Packages
- Waivers and Deviations

ORGANIZATION

At TRW, software quality assurance functions are performed in an organization called Product Assurance (see Figure 1) which is headed by a vice president level staff director. The dual role of the Product Assurance organization is quality assurance and configuration management, as it has been discovered that both functions share common characteristics.

1. They perform staff oriented functions.
2. The performance of their functions is often times more credible when done by an independent organization.
3. Staff personnel share many aptitudinal characteristics (e.g., close attention to detail, preference for wide visibility tasks).

The project PA staff (Figure 2) is often headed by an Assistant Program Manager (APM) for Product Assurance who has responsibility for two project functions: quality assurance and configuration management. The APM for Product Assurance receives project direction from the project manager, yet he and his staff retain their organizational independence from the project by reporting functionally to the Product Assurance Organization.

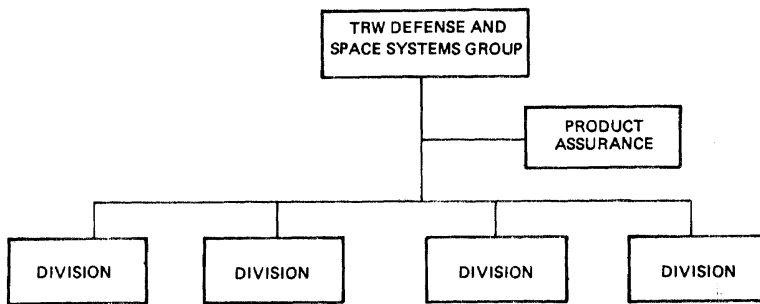


Figure 1. Corporate Organizational Structure

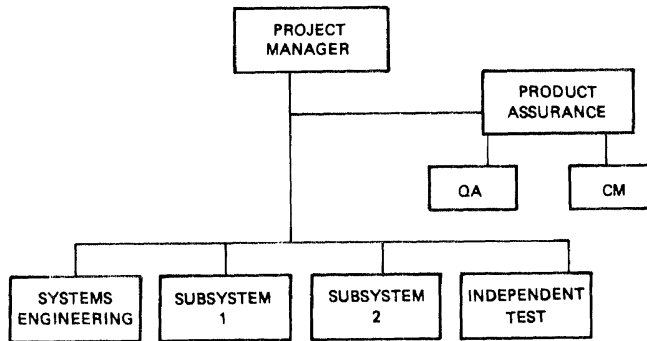


Figure 2. Project Organizational Structure

BENEFITS

The benefits of software QA seem to accrue exponentially with the size of the project. This may be caused by the fact that the larger the project size is, the further removed the project manager is from the development activity. The benefits that TRW has received are:

1. Provides increased management visibility into the development process through reviews and audits.
2. Reduction of project risk through better requirements traceability and a more disciplined and thorough testing.
3. Enforcement of software standards.
4. Centralization of software tools development and maintenance.
5. Centralization of QA records (problem reports, deviations and waivers, reviews and audits, test inspection reports, etc.).
6. A skills center for personnel with multi-project visibility who are better able to prepare project plans and procedures.
7. An independent group assuring that deliverable items meet contractual requirements.

LESSONS LEARNED

Probably the largest lesson learned is that one key to the successful development of software is the employment of a strong QA activity. It is TRW's experience that the benefits are well worth their price. Specific lessons learned with regard to the implementation of a QA program are:

1. Be sure there is adequate QA participation during the proposal and contract definition periods.
2. It's easier to hire personnel knowledgeable in software and train them in QA, than to hire QA personnel and train them in software.
3. Plan to perform the first audit very early in the development process. This leaves adequate time for corrective action.
4. Announce your intention to audit well before it occurs. The object of an audit is not to find problems, but to assure that it was done right.
5. Prepare for audits by constructing an audit checklist, and distribute the checklist to the area to be audited during the announcement of the intent to audit. This may eliminate subjective assessments by various auditors, and informs the audited party of the exact scope and depth of the audit.
6. Develop a deep and thorough relationship with each project sub-group by assigning QA engineers on a long term basis. Allow QA engineers to colocate with the software developers so they can more fully understand the daily problems of other project members.

With regard to software tools, specific lessons have been learned, and are discussed separately. First it is important to state that tools by themselves do not produce reliable software. This disclaimer is important because there have been both managers and programmers who are quick to blame a tool for the failure of their software to meet a particular goal. Second, the experience with tools at TRW has shown that programmers are curious by nature and are eager to use tools so long as the tools are user oriented, and their output is helpful to the programmers. Third, design, development, test, and documentation effort of tools should entail the same rigor as deliverable software. While this may seem superfluous to some, one must realize that except for very special one-time quickies, the hope for most tools is that they become a permanent part of a tools library and that they become available for use by many projects and organizations. As such, the tools will be widely distributed and modified to fit specific project peculiarities. One quick way for the tool to die is for its maintenance and modification to be made impossible by poor or nonexistent design documentation and in-line comments. Fourth, tools should be coded in a higher order language and in such a way as their portability from one computer system to another not entail a major rework of the tool. System peculiar functions (for example, bit manipulation, file handling, input/output, etc.) should be modularized and well documented. Fifth, tools should be designed with as much flexibility as possible in three areas: input options, processing options, and report options. Input flexibility is important so that the tool can be used on several projects and/or programming languages. Processing options allow the user to guide the tool to the specific problem area, or to solve a problem under an outside constraint (e.g., cost of each run, memory limitations, etc.). Report options are important because besides eliminating expensive print, it focuses the reader's attention on the information he requested.

CONCLUSION

In the early years of its existence, the software QA office spent most of its energy defining those areas where it could benefit the software development processes most effectively. The above list of QA functions is a derivative of this effort. In 1972, QA began its first dedicated support of a software project: a five year, \$100 million program. Currently, there is dedicated QA support on almost every large software project at TRW. Last year the Systems Engineering and Integration Division's executive office formally published a set of comprehensive software policies and procedures, many of which were derived from QA recommendations. These policies and standards are now being followed by all new software projects in that division. The Product Assurance organization considers this a significant achievement.

PROGRAM MUTATION AS A TOOL FOR MANAGING
LARGE-SCALE SOFTWARE DEVELOPMENT

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INTRODUCTION

Several approaches to aid in the design, implementation and debugging of large-scale software have recently emerged. Examples are restricted modularization (14), structured programming (14), and program verification (9,10). However helpful they may be to programmers and low-level managers, the effects of these techniques cannot be utilized throughout a software project management hierarchy since they are qualitative rather than quantitative: managers should not be expected to understand code and/or sophisticated mathematics.

In this paper we explain how an important phase of software development, testing, can be managed effectively by use of the new program testing approach known as *program mutation* (15). Program mutation provides as a side effect the qualitative type of information that managers need to monitor software development and personnel performance. The basic idea is: given a program module and its test data, program mutation provides a measure, in terms of a percentage, of how "well" the data actually tests the module. The higher the percentage, the more adequately the program has been tested. A program mutation system produces the percentage and users increase the measure by either augmenting the data in a controlled fashion or by answering "hard" questions about the module which are posed by the system. This process iterates until a satisfactory testing percentage is obtained. Meanwhile, the program mutation system records all the involved information in a data base which can be queried at any time by members at all levels of the project hierarchy to obtain reports containing relevant information on the project's testing status. For example, the project manager may wish to know only the testing percentages of all program modules while a programmer may wish to review in detail some or all of the questions and answers previously recorded for a given module.

In section 2 we detail the theory of program mutation as a program testing tool. Section 3 explains what types of information various members of the project hierarchy would draw from the mutation system and how that information would be used as a management tool. These concepts are illustrated in terms of a hypothetical compiler construction project. Finally, in section 4 we present another application of program mutation: monitoring software procurement.

THE PROGRAM MUTATION METHODOLOGY

Program testing is an inductive science which addresses the following fundamental question:

"If a program is correct on a finite number of test cases,
is it correct in general?"

Finite test data which implies general correctness is called *adequate test data* and since adequate test data cannot in general be derived algorithmically (4) program testing cannot be deductive. Recently, *path analysis* (1,2,5,6) and *symbolic execution* (7,8) have emerged as methods which allow one to gain confidence in one's test data's adequacy. Although as with any inductive science, it is possible to make false inferences with path analysis (3), the basic idea is undeniable: test data which exercises all flowchart control paths of a program at least once must be better than test data which doesn't. Symbolic execution is associated to path analysis since, among other things, it attempts to derive test data which exercises all paths of a program.

Unlike previous software reliability methods, in program mutation we make the
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following assumption:

Experienced programmers write programs which are either correct or are "almost" correct.

That is, in the mutation terminology,

If a program is *not* correct, then it is a "mutant" - it differs from a correct program by simple well-understood errors.

There is empirical evidence which supports this natural premise (11).

Boehm has found (12) that errors fall into three categories: clerical, logical, and misunderstanding of specifications. In the above assumption we do not explicitly mention errors due to programmers misunderstanding specifications; rather, it appears we are dealing exclusively with clerical errors. While a system which would solve the clerical error problem would be quite useful, program mutation does even more: indeed, below we explain how the use of the program mutation methodology can lead to the detection of all three error types.

With the "experienced programmer assumption", the mutation method is: take a program P which is correct on some test data T and subject it to a series of *mutant operators*, thereby producing mutant programs which differ from P in very simple ways. For example, if

I = I+1

is a statement in P, then

I = I-1

I = I+2

I = I+0 (i.e., a no-op)

are all simple changes which lead to three mutants of P. The mutant programs are then executed on T. If all mutants give incorrect results then it is very likely that P is correct (i.e., we can infer with high confidence that T is adequate). On the other hand, if some mutants are correct on T then we can infer that either:

- (1) The mutants are equivalent to P,
- (2) The test data T is inadequate, or
- (3) The program P is incorrect.

If it cannot be determined that P is incorrect from this information, then T must be augmented and the mutation method re-applied in an attempt to make the non-equivalent mutants which are correct on T subsequently fail. This augmentation process forces the programmer to examine P in detail with respect to the mutants.

At first glance it would appear that if T is determined adequate by mutation analysis, then P might still contain some complex errors which are not explicitly mutants of P. To this end there is a *coupling effect* which states:

Test data on which all simple mutants fail is so sensitive that it is highly likely that all complex mutants must also fail.

That is, if a program passes tests for all possible simple errors then it has been implicitly tested for all possible complex errors. It is in this effect that the power of program mutation to detect the so-called logical errors of Boehm (12) is revealed. Experiments which substantiate the coupling effect are reported in (13).

Using program mutation as a tool for obtaining reliable software is a highly interactive process whose success depends in part on human judgement. Due to the following issues, the programmer must re-examine in critical detail both his program and its specifications and why he made the decisions that led to the construction of his program. The crucial issues which must be addressed by the users include:

- (1) Which mutant operators should be applied to the program?
- (2) Are the program and its mutants correct on the given test data?
- (3) Is a given mutant equivalent to the program?

It is here that specifications errors are discovered. Note that it is possible for a

mutation system to provide the users with information which greatly facilitates resolving these issues: indeed, a mutation system can even resolve them automatically in some cases.

In using a program mutation system, a programmer specifies to the system his program, test data, and the mutant operators he wishes to be applied. The system then generates and executes the mutants on the test data and produces a report indicating which mutants are correct on the given test data. The determination of mutant correctness is done in one of two ways: (1) by direct comparison of the mutant output with the program's output, or (2) by a user-supplied algorithm which examines the output of the mutant. In both cases the system asks the user whether or not the program is acceptable on the test data. However, determination of mutant failure is done by the system.

Upon examining the report, the user may re-run the system and augment his test data in an attempt to make the remaining mutants fail. He may also specify that additional mutant operators be applied to the program. The system produces another report of the same nature as the first for the user to examine. This cycle continues until the user is satisfied that his current test data adequately tests his program.

MANAGEMENT ASPECTS OF PROGRAM MUTATION

Successful large-scale programming projects rely on a hierarchical flow of information and decisions. A fragment of such a project structuring is represented in figure 1. In addition, there is a recognizable time-ordering of events for gathering

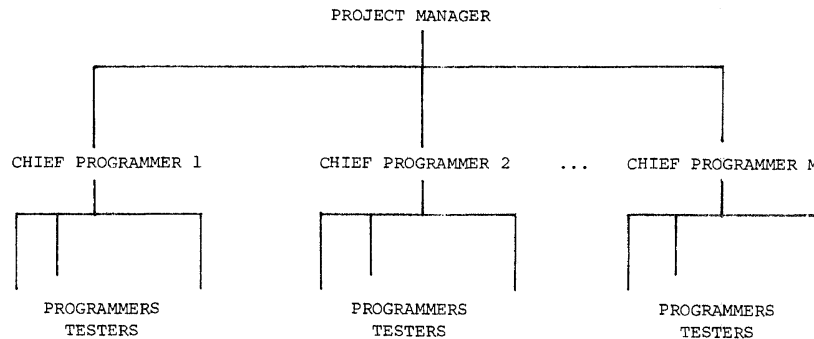


Figure 1. Hierarchical Management Organization

information and making decisions which correlates with the hierarchical management structure. Events such as "decide input file structure", "gather documentation from the submodules of module M1", "begin testing module M5" provide transformations of the programming task, replacing the as yet incomplete project with the next stage as determined by the most current information. The management hierarchy generally parallels the modular decomposition of the programming task. This can be seen directly in figure 2 where we illustrate a decomposition of a multiple pass compiler.

During the test phase of the project the mutation system records a wealth of information in its data base and this data is used to produce reports which directly influence decision-making throughout the project hierarchy. The type of information drawn from the mutation system and its uses vary depending on the project hierarchy level of the querrier. In this section we sketch some possibilities for the three levels illustrated in figures 1 and 2. Additional possibilities can readily be imagined. The general idea is: the higher the querrier is in the project structure, the less programming oriented is the gathered information.

Project Manager's Report

The project manager periodically meets with the chief programmers to evaluate the project's testing status. Also, the assignment of personnel and the evaluation of personnel performance are done at this level. The project manager's report would contain information such as:

- (1) The name of each module.

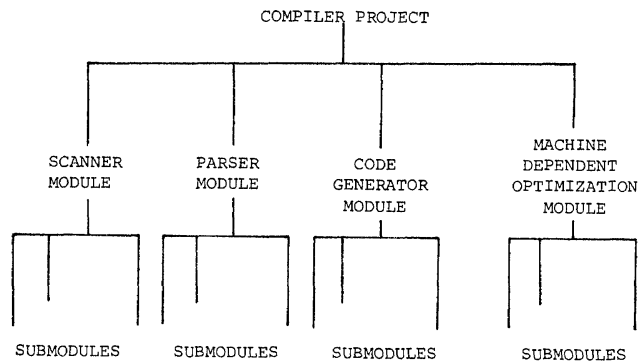


Figure 2. Modular Decomposition of a Multiple Pass Compiler

- (2) The chief programmer responsible for each module.
- (3) Plots of the mutant elimination percentage vs. time for each submodule.
- (4) For each submodule, (a) the number of mutants, (b) the number and the percentage of eliminated mutants, (c) the number and percentage of mutants deemed equivalent, and (d) the number and percentage of non-eliminated mutants.
- (5) For each module, the number and type of assigned personnel.
- (6) For each submodule, the number and type of assigned personnel.

This information can be used by the project manager to help do the following:

- (1) Monitor adherence to the project's testing pert-chart.
- (2) Decide whether an acceptable level of testing has been obtained for a given module or submodule.
- (3) Re-assignment of personnel to work on modules where the mutant elimination percentage is low.
- (4) Rewarding personnel who achieve high mutant elimination percentages.
- (5) Pinpointing responsibility for modules which fail after having been judged acceptable.

Chief Programmer's Report

A chief programmer should be familiar with the program code of all the submodules but he doesn't necessarily do any of the programming himself. He meets daily with his subordinate personnel. The type of information contained in a chief programmer's report would include:

- (1) The names and program code for each submodule of his module.
- (2) The personnel assigned to each submodule.
- (3) Plots of the mutation elimination percentage vs. time for each submodule.
- (4) The mutant operators being applied to each submodule.
- (5) For each submodule, (a) the number of mutants, (b) the number and the percentage of eliminated mutants, (c) the number and percentage of mutants deemed equivalent, and (d) the number and percentage of non-eliminated mutants.
- (6) Listings, in coded forms, of mutants determined equivalent.
- (7) Personnel responsible for classifying mutants as equivalent.

This information can be used by the chief programmer to do the following:

- (1) Suggest to the programmers additional mutant operators for a given submodule.
- (2) Ask a programmer to justify his judgement of mutants as equivalent. The chief programmer may want to know, for instance, why it does not matter if a certain variable can be mutated without changing the effect of the submodule. That is, why is his submodule so insensitive to that mutation?

- (3) Determine that a given submodule has been acceptably tested and prepare evidence on this decision for presentation to the project manager.

Programmer's and Tester's Report

These personnel are concerned mainly with the details of program code and data and thus their reports will be the most lengthy. The type of information would include:

- (1) A listing of the submodule code.
- (2) The current test data for the submodule.
- (3) The mutant operators currently being applied to the submodule.
- (4) For the submodule, (a) the number of mutants, (b) the number and the percentage of eliminated mutants, (c) the number and percentage of mutants deemed equivalent, and (d) the number and percentage of non-eliminated mutants.
- (5) Profiles of the information in (4) with respect to the mutant operators currently being applied.
- (6) Listings, in coded form, of the non-eliminated mutants.
- (7) Listings, in coded form, of the mutants determined equivalent.

This information could be used by programmers and testers to do the following:

- (1) Augment the current test data so as to eliminate mutants on the next mutation run.
- (2) Augment the set of applied mutant operators for the next mutation run.
- (3) Classify non-eliminated mutants as equivalent.
- (4) Determine that the submodule has been adequately tested and prepare evidence of this for presentation to the chief programmer.

SOFTWARE PROCURMENT ASPECTS OF PROGRAM MUTATION

Government agencies and profit making industries are currently finding that purchasing software from specialized software vendors is more economical than in-house development. The contracts generally consist of the specifications for the software and a date on which the software and test data on which the software meets the specifications are to be delivered. Occasionally, some test data is given with the specifications.

Two problems for the contractor are apparent in the above scheme: (1) at any time during the contract period the purchaser has no indication as to how "close" the software is to being ready, and (2) upon delivery, although the software works correctly on the supplied test data, there is no way to measure the quality of the purchased software. We see program mutation as a partial solution to the first problem and as a definite solution to the second.

Since program testing is the final stage of software development, a contractor can specify that the vendor indicate at what point testing commences. Assuming that the vendor is using a mutation system, the contractor can monitor the final stage of development by having the vendor periodically report mutant elimination percentages.

To evaluate the delivered software, one can specify in contracts that the test data of modules must eliminate a certain percentage of the mutants with respect to "standard" mutant operators. Here there are many options. Software not passing this quality test may be rejected or there could be a substantial financial penalty to the vendor. In this case it is not essential that the vendor use a mutation system, only that the contractor have one available to evaluate the final product. Also, note that the contractor is not concerned with equivalent mutants; rather, a simple test (which can be entirely computerized) dependent solely on the mutant operators is used. Currently, we have little information on which mutant operators should be employed in this test; however, experiments to answer this question are underway. We have observed empirically (13,15) that the percentage of equivalent mutants tends to be about two.

SUMMARY

Program mutation is an important new tool in the field of program testing which has applications in other fields. Above it has been explained how, unlike other current programming methodologies, a program mutation system can provide quantitative information which can be used throughout the management hierarchy of a large programming project. Furthermore, program mutation has an important application in that it can be incorporated into contracts for software procurement. It provides purchasers of software with a means of measuring the quality of the delivered product.

ACKNOWLEDGEMENT

We acknowledge the work of Tim Budd and the other members of the Yale University Testing Group for help in implementing and experimenting with the prototype mutation system developed at Yale University.

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QUALITY PERFORMANCE CAN BE RATED

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Programs are being developed to exploit many published philosophies. To name a few:

1. Zero Defects (ZD)¹ programs are built around the concept that human error need not be inevitable.
2. Behavioral modification is often based on supervisory attention on what is right with quality - related performance.²
3. Time oriented action plans by an identified individual toward a specific goal are the necessary ingredients of programs that follow the "Management by Objective"³ outline.
4. Subspecies of operator error (inadvertent, technique, and willful)⁴ breaks away from the idea that motivation is a cure-all for operator controlled defects and suggests a good diagnosis of operator errors is necessary.

The one common thread in all these is people. Everyone attempts to influence people to be sensitive to quality matters under the assumption that people will react positively to quality goals and that quality levels can be improved if they can be measured and tracked.

However, how often the cry "the quality was bad on the last lot but: (1) The information was too late and, (2) It didn't have the detail necessary to correct the problem".

These statements underline the basic problem of programs that collect information but do not adequately communicate it so that timely corrective action can be taken. Many times the course of action is perfectly clear to the author of the report but does not follow the basic truth that was expressed by the late Harold F. Dodge at his address to the A.S.Q.C. 27th Annual Technical Conferences. "If you want a method used, keep it simple."

This paper describes a successful program that provides timely information to the production people and makes it simple enough for everyone to understand. It is supported by the Quality Creed issued by the president of the company. The opening statement of the Creed is "More than any other single factor, the quality of Pako products, parts, and accessories and the degree of customer satisfaction with these products will determine the ultimate growth and future of our corporation".

OBJECTIVE

The objective of the quality rating system at Pako was to establish a daily/weekly working tool for production and a trend analysis report. For management the longer range objective was to establish the quality level base so that a Breakthrough goal could be set and programs for accomplishing it could be developed.

More specifically, the quality rating had to do all of the following:

1. Be consistent regardless of who reported the information
2. Be insensitive to machine complexity
3. Be understandable to all levels in the company
4. Be able to identify quality trends in a daily, weekly, monthly, and quarterly basis
5. Be able to analyze quality trend in the following matrix:
 - 5.1 By defect category
 - 5.2 By machine
 - 5.3 By foreman

COMPANY PROFILE

Pako produces specialized equipment and controls used in the processing, printing and packaging of sensitized materials for the photographic, graphic arts, and x-ray fields. The equipment specifications are highly dependent on changes in the sensitized materials industry, resulting in a need for multiple models and frequent design changes in equipment produced by Pako.

The company has a long standing good quality image. This image was unfortunately too often protected in the field by fixes made by the field service organization during installation before the customer was aware of any problem. These fixes signalled the need for quality improvement.

Another factor that demanded a more organized approach to quality was the rapid expansion of highly complex products being developed by Design Engineering. The market demanded more speed and features, thus, electronics were being substituted for the electro-mechanical controls.

Executive management set an objective: Establish quality assurance at Pako.

The objective was complicated by the fact that Pako is a rather complex company. It manufactures an extremely wide variety of equipment and utilizes many manufacturing technologies under one roof. While not a complete list the following illustrates my point.

1. The functional requirements of equipment manufactured include:
 - 1.1 The positioning and cutting of film and prints at the rate of 7 per second
 - 1.2 The transporting of film and photographic paper through chemistry without damage
 - 1.3 The sensing, color and exposure correcting, and exposing of photographic prints at the rate of 5000 an hour.
 - 1.4 The automatic sorting, pricing, invoicing, and packaging of film, prints and advertising material
 - 1.5 The ability to function over many years in an environment of highly corrosive photographic chemicals
2. The manufacturing technology employed includes:
 - 2.1 The use of tape controlled and standard types of sheet metal and welding equipment on cold roll steel, aluminum, stainless steel and titanium.
 - 2.2 The use of tape controlled and standard types of machines for machining and grinding cold roll steel, aluminum, stainless steel, castings, plastic, phenolics, and brass to tolerances as close as $\pm .0002$.
 - 2.3 The use of electrostatic painting and other standard finishing equipment for epoxy painting, plating, anodizing, passivating, black oxide, and electro-polishing of parts.
 - 2.4 The use of programmable and standard electronic test equipment for inspecting and troubleshooting TTL, CMOS; and microprocessor type P.C. boards as well as electro/mechanical control panels.

Quality improvement was needed, and it had to be done at a minimal initial increase in cost. The long range goals were to reduce cost (as a percent of sales) and improve quality.

QUALITY RATING BASIS

The basis of the Pako's Quality Rating system is to relate reportable errors on a weighted base. A minor error is defined as something that might irritate a customer but he could still get his machine in operation without any delay. A major error is one which could cause delay in getting a machine operational but which could be repaired with available tools and parts. A critical error is one which causes a major machine failure and could require major part replacement or even the replacement of the entire machine.

The quality rating (Q.R.) is the combination of the number of defects found on the machine as received from the assembly line, the weighted multipliers assigned to the type of error, times the correction factor assigned to each machine and dependent on its complexity. The results are expressed as the estimated percentage defective. This is subtracted from 100 so that the positive effect of reporting good units is reflected in the quality rating. (Fig. 1)

This numeric rating is further categorized into narrative levels of quality. (Note: These are listed on the left side on graph, Fig. 1)

The unique part of this rating system is the way the correction factor for machine complexity was developed. Ideally, the total bill of material, assembly tasks, type of equipment, and numbers of different technologies should be quantified. However, this is very costly and time consuming; therefore, the following technique was used.

1. All types of machines were reviewed as to the number of potential inspection error categories that were represented. (Table I)
2. The machines were reviewed as though they were of modular construction, i.e. electrical panel was treated as though it were a complete unit within itself. Thus, for example, a wiring error could occur in the panel as well as on component parts of the machine thus multiple wiring errors could be reported on one machine.
3. Selected machine types were rated in order of descending complexity by 12 people who had a working knowledge of all company products. (Table II)
4. This list was summarized and the total inspection points (categories listed below) were adjusted so that the total potential quality impact (sum of categories/times/impact multiplier) was consistent with the machine complexity.

Table I. INSPECTION CATEGORIES

<u>Minor</u>	<u>Major</u>	<u>Critical</u>
1. Appearance, dents, scratches	6. Improper electrical connections	9. Hi-pot failure assembly error
2. Neatness of harness/wiring	7. Adjustments incomplete	10. Miswired electrical connection
3. Missing items	8. Leaks	11. Mechanical malfunction
4. Fastenings loose/missing		
5. Plumbing error		

Table II. MACHINE COMPLEXITY

<u>Machine</u>	<u>Total Impact</u>	<u>Control Factor</u>
Photopacker	244	.41
Mach II Printer	212	.47
Cine Film Processor	207	.48
Graphic Arts Processor	148	.68
B/C 24 Printer	118	.85
Medical X-ray Processor	76	1.32
Micro-Film Processor	67	1.49
Print Dryer	67	1.49
Washer	37	2.70

The total impact was divided into an arbitrary base of 100. The resulting number was called the control factor. The purpose of this control factor was to partially reduce the effect of each error on the quality rating of complex machines and, likewise, increase it on simple machines.

The major significance in recognizing machine complexity comes in selling the number to the production foreman. If he knows that his complex machines with hundreds of wires will not be impacted by a single error as much as a simple machine, he will agree to the quality rating number. Once this occurs, management can use the numbers for performance reviews. Quality then becomes as important to the foreman as his labor performance.

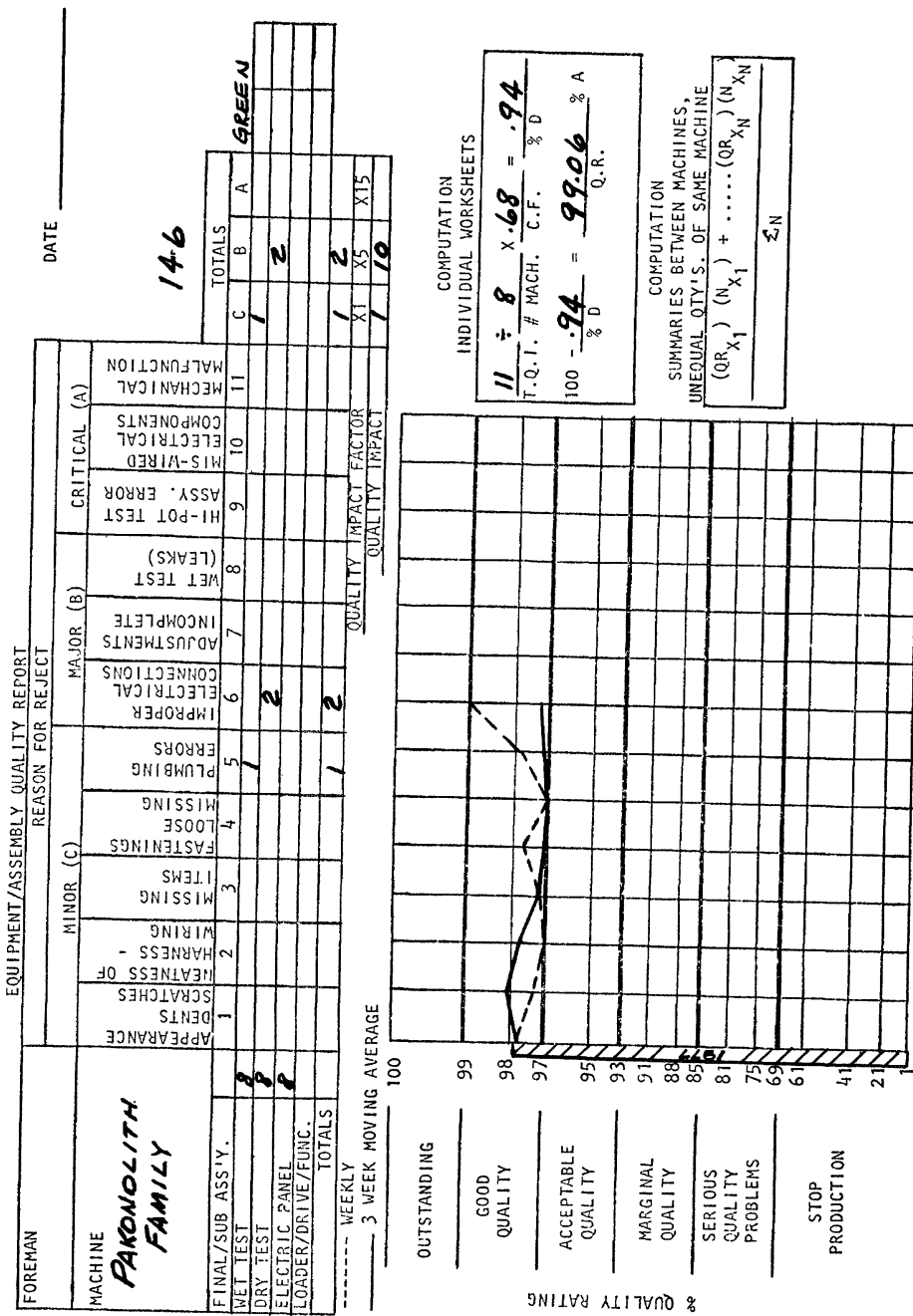


Figure 1. Equipment/Assembly Quality Report

One question comes up often. Are all errors charged to the assembly foreman? No, only errors that were considered his work are charged to him. For example, a leaking tank is not the fault of assembly but a leaking hose fitting to the tank is his responsibility.

However, the component failures are not ignored. Part numbers are included on the inspection sheets and are logged by the Quality Engineering Coordinator. Repetitive part numbers are flagged for possible corrective action. This is an aid in defining receiving inspection and fabrication faults.

The equipment/assembly quality report (Fig. 1) is distributed weekly to each foreman. The chart includes both a weekly and a three week moving average of his quality rating as well as a listing of the errors that made up the weekly rating.

Monthly a similar report by foreman and by the total assembly department is distributed to all management.

RESULTS

Based on two full years, the program has tracked the following results.
(Table III)

Table III. 1977 vs. 1976 Machine Quality Analysis

Quantity		Quality Rating		Errors/Mach.		Spoilage (% Std. Cost)		Field Prob. Per Mach.	
'77	'76	'77	'76	'77	'76	'77	'76	'77	'76
5450	4126	96.42	96.00	.58	.66	1.46	2.23	.09	.19
+32.1%		+.4%		-12.1%		-34.5%		-52.5%	

During this period, the quality rating took three dips. The first one was observed and communicated to the production organization. The trend continued until middle management implemented a corrective action program. As the problems diminished the quality rating raised and confirmed that the corrective action was successful. The second dip appeared during a heavy six week production load. The reaction by production was immediate with a resulting good quality level being maintained during the remaining four weeks of heavy production.

The third dip was observed approximately 18 months after the Q.R. program was initiated. This dip was interpreted by management as a status quo condition that could become serious if ignored. Quality management reacted by embarking on a long range quality awareness program.

Introduction of the quality awareness program was aided by using the results of the quality improvement breakthrough that was achieved on a particularly troublesome machine. The recorded errors per machine were very high on this model even though it was in continuous production. The results were as follows in Table IV.

Table IV. Improvement on a particularly troublesome machine

	ERROR CATEGORY (See Table I)											Total
	1	2	3	4	5	6	7	8	9	10	11	
1st 6 mo. (596 units)	0	0	51	110	3	23	36	128	3	40	8	402
2nd 6 mo. (586 units)	1	1	27	33	6	15	2	61	4	16	1	167
3rd 6 mo. (442 units)	0	0	5	8	6	4	0	70	1	12	1	107

During that period, the quality rating went from under 95% to over 99%.

Based on the success of improving the Q.R. of this machine, the time had arrived to embark on J. M. Juran's Breakthrough philosophy. The Quality Rating had proven that the production organization was under control. The time for a Breakthrough into new levels was also appropriate since the measurement tools had been proven and the foreman and the quality control personnel had faith in the Q.R. numbers.

ADDITIONAL BENEFITS

The technology of the rating system and the reports have been made applicable to other areas of the company. Examples included the following areas:

1. Stockroom, shipping, warehouse and other materials functions
2. Fabrication departments (by foreman and work center)

It has provided a means for recognizing good work and provides tools for future improvements.

A secondary impact has been realized for agencies such as OSHA and UL. The records and corrective action programs generally indicate to an outside inspector that the company is responsive. This alone has built confidence and reduced outside inspector involvement with the company.

The evidence of improvements in quality trends also aided in more effective manpower utilization. No longer does a single reported field failure create an unjustified "Quality Improvement Program" at the expense of preventative efforts.

SUMMARY

The Pako Quality Creed also contains the statement "The true existence of quality control is in the attitude and commitment demonstrated by all employees".

The idea of making quality everybody's business is beginning to unfold. With it is the theme "You Have a Hand in Quality".

Tied to the theme is the quality rating system which has the ability to recognize those who achieve and help those who don't.

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ACCEPTANCE SAMPLING DECISION RULES FOR ATTRIBUTES

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INTRODUCTION

In census and survey data processing many quality control rules have been used to assure continued quality after initial qualification in the work of coders, typists or keyers. An example of such a rule is, "A worker remains qualified if s successive work lots are accepted within a maximum of d inspected." The purpose of this paper is to summarize the probability distributions and tables associated with some decision rules of this type and to examine a new rule which has recently been used in Census Bureau quality control decision processes. This paper reviews and continues publications on the same topic by George Minton and others. A selected bibliography is included.

ASSUMPTIONS

If our basic production unit is called a lot (of N items), a decision regarding acceptance or rejection of the lot is made on the basis of a sample of n items taken from the lot. We assume n to be small with respect to N so that the binomial distribution can be used to find the probability that a single lot is acceptable. Grubbs (1949) states that the lot size should be 10 to 15 times the sample size before the binomial distribution becomes an excellent approximation to the hypergeometric distribution (the exact distribution in this case).

A second assumption is that the lots themselves are of homogeneous quality with P as the true fraction defective.

Finally, we assume that inspection is error-free. In practice this assumption is approached only in most independent error detection plans. Quality control models which incorporate Type I inspection error (an inspector classifies a nondefect as a defect) and Type II error (an inspector classifies a defect as nondefective) are discussed in Lavin (1946), U. S. Bureau of the Census (1965), and Minton (1969).

Using these assumptions, the probability of accepting a work lot is

$$L_p = \sum_{x=0}^c \binom{n}{x} p^x Q^{n-x} \quad (1)$$

where c is the acceptance number and $Q=1 - P$.

DECISION RULES

Rule 1:

A worker remains qualified (survives the decision) if f or fewer work lots fail sample inspection within d inspected.

If the probability of a lot failing inspection is $(1-L_p)$, then the probability of having f or fewer failures in d lots (call this $S_{d,f}$) is computed from the binomial distribution:

$$S_{d,f} = \sum_{i=0}^f \binom{d}{i} L_p^{d-i} (1-L_p)^i \quad (2)$$

where i is the number of rejected lots failing sample inspection

(i=0,1, . . . ,f).

Given the arguments L_p , d , and f , the probability of a worker's survival is easily found using a cumulative binomial table. Minton (1970) provides such a table.

Rule 2:

A worker survives if s successive work lots are accepted within a maximum of d inspected.

The probability of a worker's survival after d work lots under this rule is not as straightforward as in Rule 1, but Burnside (1959) provides a recursion formula which Minton (1970) uses to construct a table of survival probabilities for this rule. The formula for $Q_{d,s}$ the probability of s successive acceptable work lots within a maximum of d inspected is:

$$Q_{d,s} = L_p^s + \sum_{i=1}^r M_i (L_p)^{is} (1-L_p)^i - \sum_{i=1}^{r-1} (N_i) (L_p)^{(i+1)s} (1-L_p)^i \quad (3)$$

where r is the largest integer in $\frac{d}{s}$

$$M_i = (-1)^{i+1} \binom{d-is}{i}$$

$$N_i = (-1)^{i+1} \binom{d-(i+1)s}{i}$$

Investigation of the tabular survival probabilities for Rules 1 and 2 indicates that comparable probabilities of acceptance can be attained if d is permitted to differ between rules. As opposed to the following Rules 3 and 4, these first two decision criteria require quality assessments only after multiples of d work lots are completed. This has two disadvantages: (i) after each d lots a worker has no credit (or debit) for previous work performed and (ii) a decision on quality cannot be made until d lots are completed. These effects might lead one to consider the following rules which potentially allow (except at the outset of production) a work quality decision after each work lot completed.

Rule 3:

Given C points initially, a point is added when a worker's lot is accepted or deducted when a lot is rejected. If the point total remains greater than zero while working D lots, the worker remains qualified.

The probability of surviving D decisions given C initial points is originally suggested by Feller (1957) and is derived by Cook (1961). Minton (1970) used this work to provide a table of survival probabilities for this rule. The probability of survival (called $U_{D,C}$) given D, C, L_p is:

$$U_{D,C} = \sum_{i=F}^D \left[\binom{D}{\frac{D-i}{2}} - \binom{D}{\frac{D-i}{2} - C} \right] L_p^{\frac{D+i}{2}} (1-L_p)^{\frac{D-i}{2}} \quad (4)$$

where $F = D-2 \cdot \lceil (D+C-1)/2 \rceil$ and

$\lceil \cdot \rceil$ indicates that the greatest integer in $\frac{D+C-1}{2}$ is to be used.

Rule 3 has the advantage that further study has been made concerning it. Minton and Krivitsky (1971) give a table for the expected number of points given continuance after D decisions and a table for the expected number of decisions given worker removal before D decisions. However, a disadvantage of Rule 3 is that a worker might accumulate an abundance of points thus insuring his/her continuance even if subsequent work deteriorated. This drawback plus the previously mentioned disadvantages of Rules 1 and 2 has lead to consideration of Rule 4 (the "new rule" mentioned earlier).

Rule 4:

A worker remains qualified if f or fewer work lots fail sample inspection within the last d inspected.

This criteria (i) provides for a work quality decision after each lot is completed, (ii) always considers previous work in the decision, and (iii) always decides only on the basis of the most recent work produced. Considering these attributes an attempt was made to find a closed form for the probability of survival using the arguments L_p, d, f and D (the number of the last lot worked). But due to the conditional nature of the rule, derivation did not seem as feasible as computer enumeration of possibilities. This method has produced Table I which gives $S_{d,f}$ the probability of survival after D lots based on whether f or fewer lots fail inspection within the last d lots inspected. Probabilities are given for $L_p = .05(.05)1.00$ and survival probability curves are presented in Figures 1-4.

SUMMARY

In examination of Table I and Minton's (1970) tables for Rules 1, 2, and 3 it can be seen that comparable survival probabilities can be attained using any of the four rules if d is permitted to differ between rules. In choosing a decision rule, though, the value of d and the survival probability curve might be of primary importance. Then the various advantages/disadvantages mentioned here would be of little consequence; the best rule would be found just by examining the tables. However, these four rules, their probability distributions, Table I, and some of the advantages/disadvantages of their use might help provide decision rule users with a larger informational basis by which to choose a rule.

MATERIALS

Copies of the tables, published by Minton (1970), for Rules 1, 2, and 3 are available from the author upon request. The computer program used for Table I is also available.

ACKNOWLEDGEMENT

I would like to thank Paul Pavlica, U. S. Bureau of the Census, for his programming assistance.

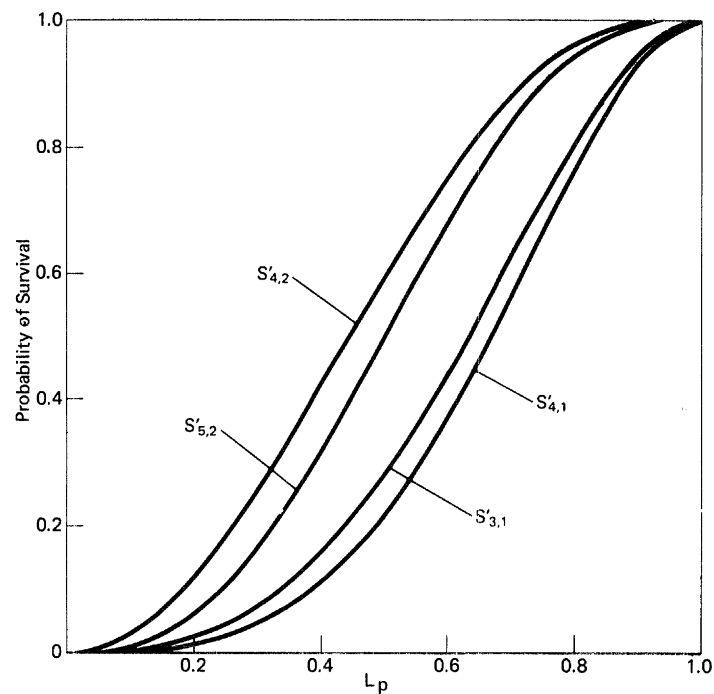


Figure 1. Probability of Survival Curves for Rule 4 when $D=5$

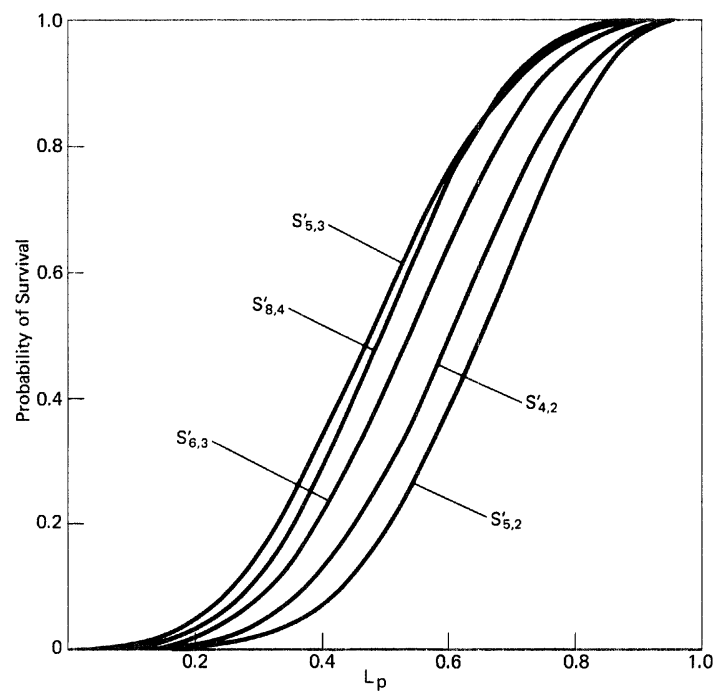


Figure 2. Probability of Survival Curves for Rule 4 when $D=10$

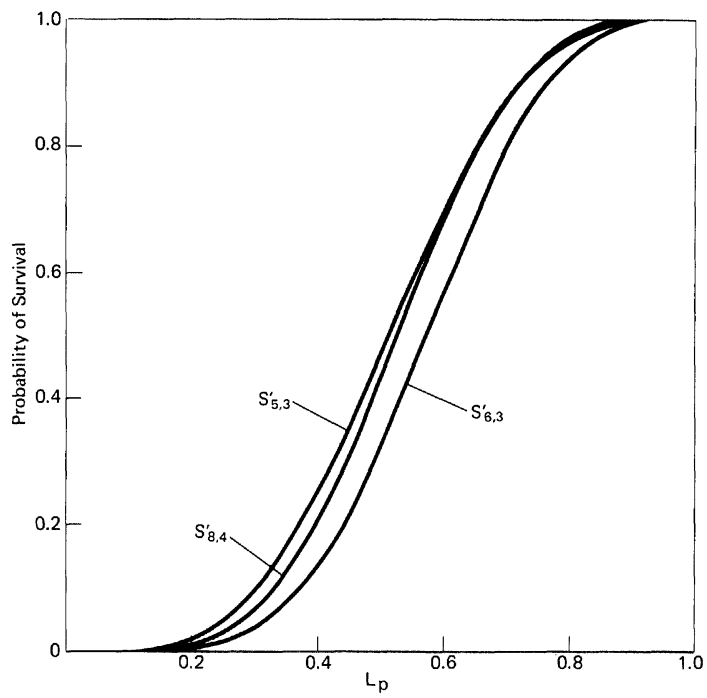


Figure 3. Probability of Survival Curves for Rule 4 when $D=12$

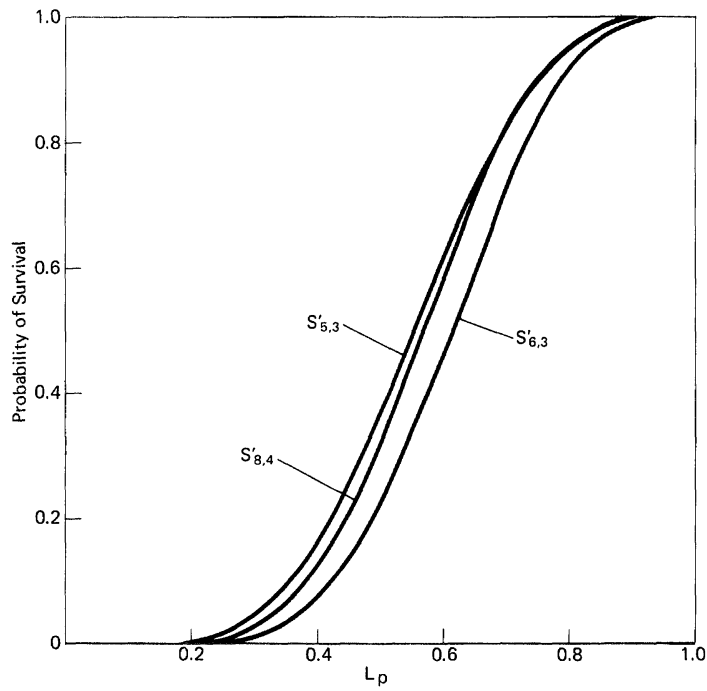


Figure 4. Probability of Survival Curves for Rule 4 when $D=15$

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CONSTRUCTION AND USE OF QUALITY CONTROL TABLES

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INTRODUCTION

The Census Bureau has many computer programs to assist in the development of sampling plans. Each computer program is for a specific type of sampling plan, i.e., single, double, sequential, Dodge, etc. These programs are usually used in conjunction with an interactive time-sharing system. Therefore, several people may use the same computer program at the same or different points in time, thereby duplicating effort. With this in mind, it is felt that a first step toward saving time and money plus having more accurate and timely information would be to create and distribute to each quality control area within the Census Bureau a set of single acceptance sampling plans. The plans are produced based on the Binomial Probability distribution and are accompanied by several other tables that would give ranges of sampling plans for specific desired AOQL, AQL, and LTPD values.

QUALITY CONTROL TABLES

Four separate tables have been constructed to facilitate the design of the quality control plans. The four tables are:

1. Operating Characteristic (OC) Curve Table

For a given sampling plan (i.e., sample size and acceptance number combination), the probability of accepting a lot and the average outgoing quality, as a function of the estimated incoming lot quality.

2. Average Outgoing Quality Limit (AOQL) Table

For a given AOQL, the sampling plans that would yield that AOQL. The AOQL is defined as the largest calculated AOQ value for the given sampling plan.

3. Acceptable Quality Level (AQL) Table

For a given AQL, the sampling plans that would yield a 5 percent α error.

NOTE: The AQL is used as a basis for some inspection systems and is commonly associated with a 5 percent α error or producer's risk. That is, the AQL is the incoming error level associated with a 5 percent probability of rejection for the given sample size (the complement of a 95 percent probability of accepting the lot) and acceptance number.

4. Lot Tolerance Percent Defective (LTPD) Table

For a given LTPD, the sampling plans (i.e., sample size and acceptance number combinations) that would yield a 10 percent β error.

NOTE: The LTPD is used as a basis for some inspection systems and is commonly associated with a 10 percent β error or consumer's risk. That is, the LTPD is the incoming error level associated with a 10 percent probability of acceptance for the given sample size (the complement of a 90 percent probability of rejecting the lot) and acceptance number.

All tables assume that all defects in the selected sample are detected (zero inspection error), and all rejected work units are 100 percent rectified with all defects within the work units being detected and corrected. [2]

SPECIFICATIONS FOR DERIVING QUALITY CONTROL TABLES

Operating Characteristic (OC) Curve Table

The Operating Characteristic (OC) Curve Table provides the probability of accepting a given lot and the average outgoing quality as a function of the lot quality (incoming error rate) for given sample size and acceptance number combinations.

The probability of acceptance was computed using the Binomial Probability formula:

$$P_c(p) = \sum_{x=0}^c \binom{n}{x} \cdot p^x \cdot (1-p)^{n-x}$$

where,

$P_c(p)$ = probability of acceptance
 n = sample size
 c = acceptance number
 p = lot quality or incoming error rate

Then, given the probability of acceptance, the average outgoing quality (AOQ) was calculated using the formula:

$$AOQ = p \cdot P_c(p)$$

NOTE: The Binomial Probability distribution was used as an approximation to the hypergeometric distribution by making the following assumptions:

1) the work unit, N , is large, 2) the work unit size, N , is substantially larger than the sample size, n , and 3) the binomial distribution represents the universe even though one particular individual's or machine's quality will vary from hour to hour, day to day, etc. [1], [2], [3], [4]

Average Outgoing Quality Limit (AOQL), Acceptable Quality Level (AQL), and Lot Tolerance Percent Defective (LTPD) Tables

The Average Outgoing Quality Limit (AOQL), Acceptable Quality Level (AQL), and Lot Tolerance Percent Defective (LTPD) Tables were all produced using the Binomial Probability formula.

The computer program to compile the AOQL, AQL, or LTPD Tables used the same data, but each was sorted separately. Each table used as its primary sort key the AOQL, AQL, or LTPD value, respectively. The secondary sort key in all tables was the acceptance number.

Value Ranges

The value ranges for the Quality Control Tables are as follows:

<u>Variable</u>	<u>Range</u>	<u>Increment</u>
sample size (n)	10 to 200	1
	205 to 350	5
	360 to 500	10
acceptance number (c)	0 to $[0.15(n)+1]$	1

Table 1

Operating Characteristics (OC) Curve Table

[illegible]

Table 2

Sample Size Ranges for given Acceptance Numbers and Average Outgoing Quality Limits

Acceptance Number (c)	Average Outgoing Quality Limit (AOQL) Percent										Acceptance Number (c)
	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10.0	
0	10 - 14	10 - 13	10 - 12	10 - 11	10	10	10	10	10	10	0
1	15 - 24	15 - 22	15 - 20	15 - 19	15 - 18	15 - 17	15 - 16	15 - 15	15 - 14	15 - 13	1
2	25 - 35	25 - 32	25 - 30	25 - 29	25 - 28	25 - 27	25 - 26	25 - 25	25 - 24	25 - 23	2
3	36 - 46	36 - 42	36 - 40	36 - 39	36 - 38	36 - 37	36 - 36	36 - 35	36 - 34	36 - 33	3
4	47 - 57	47 - 53	47 - 50	47 - 49	47 - 48	47 - 47	47 - 46	47 - 45	47 - 44	47 - 43	4
5	58 - 69	58 - 65	58 - 62	58 - 61	58 - 60	58 - 59	58 - 58	58 - 57	58 - 56	58 - 55	5
6	70 - 81	70 - 77	70 - 74	70 - 73	70 - 72	70 - 71	70 - 70	70 - 69	70 - 68	70 - 67	6
7	82 - 94	82 - 90	82 - 87	82 - 86	82 - 85	82 - 84	82 - 83	82 - 82	82 - 81	82 - 80	7
8	95 - 106	95 - 102	95 - 99	95 - 98	95 - 97	95 - 96	95 - 95	95 - 94	95 - 93	95 - 92	8
9	107 - 119	107 - 114	107 - 111	107 - 110	107 - 109	107 - 108	107 - 107	107 - 106	107 - 105	107 - 104	9
10	120 - 132	120 - 127	120 - 124	120 - 123	120 - 122	120 - 121	120 - 120	120 - 119	120 - 118	120 - 117	10
11	133 - 145	133 - 140	133 - 137	133 - 136	133 - 135	133 - 134	133 - 133	133 - 132	133 - 131	133 - 130	11
12	146 - 158	146 - 153	146 - 150	146 - 149	146 - 148	146 - 147	146 - 146	146 - 145	146 - 144	146 - 143	12
13	159 - 172	159 - 166	159 - 170	159 - 169	159 - 168	159 - 167	159 - 166	159 - 165	159 - 164	159 - 163	13
14	173 - 185	173 - 180	173 - 183	173 - 182	173 - 181	173 - 180	173 - 179	173 - 178	173 - 177	173 - 176	14
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16	200 - 212	200 - 207	200 - 210	200 - 209	200 - 208	200 - 207	200 - 206	200 - 205	200 - 204	200 - 203	16
17	213 - 226	213 - 220	213 - 223	213 - 222	213 - 221	213 - 220	213 - 219	213 - 218	213 - 217	213 - 216	17
18	227 - 240	227 - 234	227 - 237	227 - 236	227 - 235	227 - 234	227 - 233	227 - 232	227 - 231	227 - 230	18
19	241 - 254	241 - 248	241 - 251	241 - 250	241 - 249	241 - 248	241 - 247	241 - 246	241 - 245	241 - 244	19
20	255 - 268	255 - 262	255 - 265	255 - 264	255 - 263	255 - 262	255 - 261	255 - 260	255 - 259	255 - 258	20
21	269 - 282	269 - 276	269 - 279	269 - 278	269 - 277	269 - 276	269 - 275	269 - 274	269 - 273	269 - 272	21
22	283 - 296	283 - 290	283 - 293	283 - 292	283 - 291	283 - 290	283 - 289	283 - 288	283 - 287	283 - 286	22
23	297 - 310	297 - 304	297 - 307	297 - 306	297 - 305	297 - 304	297 - 303	297 - 302	297 - 301	297 - 300	23
24	311 - 324	311 - 318	311 - 321	311 - 320	311 - 319	311 - 318	311 - 317	311 - 316	311 - 315	311 - 314	24
25	325 - 339	325 - 332	325 - 335	325 - 334	325 - 333	325 - 332	325 - 331	325 - 330	325 - 329	325 - 328	25

Table 3

Sample Size Ranges for given Acceptance Numbers and Acceptable Quality Level

Acceptance Number (c)	Acceptable Quality Level (AQL) Percent										Acceptance Number (c)
	5.5%	6.0%	6.5%	7.0%	7.5%	8.0%	8.5%	9.0%	9.5%	10.0%	
0	10 - 14	10 - 13	10 - 12	10 - 11	10	10	10	10	10	10	0
1	15 - 24	15 - 22	15 - 20	15 - 19	15 - 18	15 - 17	15 - 16	15 - 15	15 - 14	15 - 13	1
2	25 - 35	25 - 32	25 - 30	25 - 29	25 - 28	25 - 27	25 - 26	25 - 25	25 - 24	25 - 23	2
3	36 - 46	36 - 42	36 - 40	36 - 39	36 - 38	36 - 37	36 - 36	36 - 35	36 - 34	36 - 33	3
4	47 - 57	47 - 53	47 - 50	47 - 49	47 - 48	47 - 47	47 - 46	47 - 45	47 - 44	47 - 43	4
5	58 - 69	58 - 65	58 - 62	58 - 61	58 - 60	58 - 59	58 - 58	58 - 57	58 - 56	58 - 55	5
6	70 - 81	70 - 77	70 - 74	70 - 73	70 - 72	70 - 71	70 - 70	70 - 69	70 - 68	70 - 67	6
7	82 - 94	82 - 90	82 - 87	82 - 86	82 - 85	82 - 84	82 - 83	82 - 82	82 - 81	82 - 80	7
8	95 - 106	95 - 102	95 - 99	95 - 98	95 - 97	95 - 96	95 - 95	95 - 94	95 - 93	95 - 92	8
9	107 - 119	107 - 114	107 - 111	107 - 110	107 - 109	107 - 108	107 - 107	107 - 106	107 - 105	107 - 104	9
10	120 - 132	120 - 127	120 - 124	120 - 123	120 - 122	120 - 121	120 - 120	120 - 119	120 - 118	120 - 117	10
11	133 - 145	133 - 140	133 - 137	133 - 136	133 - 135	133 - 134	133 - 133	133 - 132	133 - 131	133 - 130	11
12	146 - 158	146 - 153	146 - 150	146 - 149	146 - 148	146 - 147	146 - 146	146 - 145	146 - 144	146 - 143	12
13	159 - 172	159 - 166	159 - 170	159 - 169	159 - 168	159 - 167	159 - 166	159 - 165	159 - 164	159 - 163	13
14	173 - 185	173 - 180	173 - 183	173 - 182	173 - 181	173 - 180	173 - 179	173 - 178	173 - 177	173 - 176	14
15	186 - 199	186 - 193	186 - 196	186 - 195	186 - 194	186 - 193	186 - 192	186 - 191	186 - 190	186 - 189	15
16	200 - 212	200 - 207	200 - 210	200 - 209	200 - 208	200 - 207	200 - 206	200 - 205	200 - 204	200 - 203	16
17	213 - 226	213 - 220	213 - 223	213 - 222	213 - 221	213 - 220	213 - 219	213 - 218	213 - 217	213 - 216	17
18	227 - 240	227 - 234	227 - 237	227 - 236	227 - 235	227 - 234	227 - 233	227 - 232	227 - 231	227 - 230	18
19	241 - 254	241 - 248	241 - 251	241 - 250	241 - 249	241 - 248	241 - 247	241 - 246	241 - 245	241 - 244	19
20	255 - 268	255 - 262	255 - 265	255 - 264	255 - 263	255 - 262	255 - 261	255 - 260	255 - 259	255 - 258	20
21	269 - 282	269 - 276	269 - 279	269 - 278	269 - 277	269 - 276	269 - 275	269 - 274	269 - 273	269 - 272	21
22	283 - 296	283 - 290	283 - 293	283 - 292	283 - 291	283 - 290	283 - 289	283 - 288	283 - 287	283 - 286	22
23	297 - 310	297 - 304	297 - 307	297 - 306	297 - 305	297 - 304	297 - 303	297 - 302	297 - 301	297 - 300	23
24	311 - 324	311 - 318	311 - 321	311 - 320	311 - 319	311 - 318	311 - 317	311 - 316	311 - 315	311 - 314	24
25	325 - 339	325 - 332	325 - 335	325 - 334	325 - 333	325 - 332	325 - 331	325 - 330	325 - 329	325 - 328	25

Table 4

Sample Size Ranges for Given Acceptance Numbers and Lot Tolerance Percent Defective

Acceptance Number (c)	Lot Tolerance Percent Defective (LTPD) Percent										Acceptance Number (c)
	10.5%	11.0%	11.5%	12.0%	12.5%	13.0%	13.5%	14.0%	14.5%	15.0%	
0	21 - 35	20 - 33	19 - 32	18 - 30	17 - 28	16 - 27	15 - 26	14 - 25	13 - 24	12 - 23	0
1	36 - 48	34 - 46	33 - 44	31 - 42	30 - 40	29 - 39	27 - 37	26 - 36	24 - 34	23 - 33	1
2	49 - 61	47 - 58	45 - 56	43 - 53	41 - 51	40 - 49	38 - 47	37 - 45	35 - 44	34 - 42	2
3	62 - 74	59 - 70	57 - 67	54 - 64	52 - 61	50 - 59	48 - 57	46 - 55	45 - 53	43 - 51	3
4	75 - 86	71 - 82	68 - 78	65 - 75	62 - 71	60 - 69	58 - 66	56 - 64	54 - 61	52 - 59	4
5	87 - 97	83 - 93	79 - 89	76 - 85	72 - 81	70 - 78	67 - 75	65 - 72	62 - 70	60 - 67	5
6	98 - 109	94 - 104	90 - 99	86 - 95	82 - 91	79 - 88	76 - 84	73 - 81	71 - 78	68 - 75	6
7	110 - 121	105 - 115	100 - 110	96 - 105	92 - 101	89 - 97	85 - 93	82 - 90	79 - 87	76 - 84	7
8	122 - 132	116 - 126	111 - 120	106 - 115	102 - 110	98 - 106	94 - 102	91 - 98	88 - 95	85 - 91	8
9	133 - 143	127 - 137	121 - 131	116 - 125	111 - 120	107 - 115	103 - 111	99 - 107	96 - 103	92 - 99	9
10	144 - 155	138 - 147	132 - 141	126 - 135	121 - 129	116 - 124	112 - 120	108 - 115	104 - 111	100 - 107	10
11	156 - 166	149 - 158	142 - 151	136 - 145	130 - 139	125 - 133	121 - 128	116 - 125	112 - 119	108 - 115	11
12	167 - 177	159 - 169	152 - 161	146 - 154	140 - 148	134 - 142	129 - 137	124 - 132	119 - 127	114 - 123	12
13	178 - 188	170 - 179	162 - 171	155 - 164	149 - 157	143 - 151	138 - 145	133 - 140	128 - 135	124 - 130	13
14	189 - 199	180 - 190	172 - 181	165 - 174	158 - 167	152 - 160	146 - 154	141 - 148	136 - 143	131 - 138	14
15	200 - 210	191 - 200	182 - 191	175 - 183	168 - 176	161 - 169	155 - 162	149 - 156	144 - 151	139 - 146	15
16	211 - 221	201 - 211	192 - 201	184 - 193	177 - 185	170 - 178	163 - 171	157 - 165	152 - 159	147 - 153	16
17	222 - 232	212 - 221	202 - 211	194 - 202	186 - 194	179 - 186	172 - 179	166 - 173	160 - 167	154 - 161	17
18	233 - 243	223 - 231	212 - 221	203 - 212	195 - 203	187 - 195	180 - 188	174 - 181	168 - 175	162 - 169	18
19	244 - 253	234 - 242	222 - 231	213 - 221	204 - 212	196 - 204	189 - 196	182 - 189	176 - 182	170 - 176	19
20	254 - 264	244 - 252	232 - 241	222 - 231	213 - 221	205 - 213	197 - 204	190 - 197	183 - 190	177 - 184	20
21	265 - 275	255 - 262	242 - 251	232 - 240	222 - 230	214 - 221	205 - 213	198 - 205	191 - 198	185 - 191	21
22	276 - 286	266 - 273	252 - 260	241 - 249	231 - 239	222 - 230	214 - 221	206 - 213	199 - 206	193 - 199	22
23	287 - 296	277 - 283	264 - 270	250 - 259	240 - 248	231 - 238	222 - 229	214 - 221	207 - 213	200 - 206	23
24	297 - 307	287 - 293	274 - 280	260 - 268	249 - 257	239 - 247	230 - 238	222 - 229	214 - 221	207 - 214	24
25	308 - 318	298 - 303	284 - 290	269 - 277	258 - 266	248 - 256	239 - 246	230 - 237	222 - 229	215 - 221	25

<u>Variable</u>	<u>Range</u>	<u>Increment</u>
error rate (p)	0.005 to 0.250	0.005
	0.300 to 0.500	0.100
AOQL	0.005 to 0.100	0.005
AQL	0.005 to 0.100	0.005
LTPD	0.005 to 0.150	0.005

For AOQL Tables, the minimum sample size for a particular acceptance number must give an AOQL which comes as close as possible (to the nearest 0.0001) to the designated AOQL without exceeding it.

For AQL Tables, the probability of acceptance at the AQL is as close as possible but not less than 0.95 (to the nearest 0.0001) for the maximum sample size in the range for a particular acceptance number.

For LTPD Tables, the probability of acceptance at the LTPD is as close as possible but not more than 0.10 (to the nearest 0.0001) for the minimum sample size in the range for a particular acceptance number.

Output Formats

Examples of the output formats for the Quality Control Tables are shown in: Table 1 for the Operating Characteristics (OC) Curve Table; Table 2 for the Average Outgoing Quality Limit (AOQL) Table; Table 3 for the Acceptable Quality Level (AQL) Table; and Table 4 for the Lot Tolerance Percent Defective (LTPD) Table.

Use of Quality Control Tables

Each Quality Control Table may be used individually or in conjunction with the other tables. For example, if an operation has variable lot sizes and a systematic, random sample is being selected, this will thereby yield variable sample sizes. If the operation were established on the basis of a 7.00 percent AOQL, then Table 2 would indicate a series of sampling plans that would result in the desired AOQL. Further information concerning each individual sampling plan; i.e., probability of acceptance at given incoming error rate levels, could be obtained by referring to the appropriate OC Curve Table(s).

The same procedure could be followed if the quality level initially established were on an AQL or LTPD basis instead of the above-mentioned AOQL basis.

COMPUTER PROGRAMS

All calculations were performed on a Univac 1110 computer. The output data were recorded on magnetic tape and the tables were produced on a Xerox 1200 computer/printing system.

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EFFICIENT DECISIONS THROUGH RISK EVALUATION

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REVIEW OF QUALITY ENVIRONMENT

Proper management requires a balanced set of clearly defined objectives among which quality should be a major one. In Air Transport quality objectives may be summarized in safety, regularity and passenger comfort, all within an economical framework.

As a next step management decides what has to be done to reach these objectives. Although the maxim "quality cannot be inspected into a product, it has to be built in" is widely accepted by management today, the ideal condition, with no inspection required, simply does not exist in practice. Some vital quality characteristics, in particular those directly related to safety, will always have to be inspected.

However, to decide which maintenance activities may cause a critical situation if improperly performed is sometimes a rather difficult task. The incorrect installation of a gasket in the powerplant oil-system may not show up on the teststand but result in an engine failure later in operation, eventually affecting safety, regularity and passenger comfort. If the airplane stays on ground at a place where no spare powerplant nor adequate lifting facilities are available, then this little gasket has caused a real problem.

Modern Jet Aircraft have developed into very complex systems. There we have a structure containing electrical, hydraulic, water and aircystems, more and more electronics of advanced technology and high performance powerplant attached to it. On the other hand designers developed failsafe structures, systems more and more redundant and numerous built in testcircuits.

All these technical aspects have to be considered for the planning of the inspection function.

Beside the technological conditions, human factors may be of even greater influence on quality. It should be taken into consideration that

- no additional inspection orders are given by supervisors merely for their personal protection
- orders for corrective actions are not implemented the easy way by performing just an additional inspection, like an alibi that something has been done instead of solving the real problem
- "personel protection" and "alibi"-inspections do not become a general law ("it has always been done this way"), going on for years with nobody remembering the real reason for it.

The quality climate may further deteriorate due to

- inspectors who have a sort of instinct for what is an effective inspection, losing confidence in "personal protection" or "alibi"-type inspections and making individual decisions independent of management specifications
- workers motivation for quality being undermined by "over-inspection".

To cope with this broad spectrum of technical and human aspects we decided to review our inspection planning systematically. The method developed is based on risk evaluation of work performed and will be described subsequently in this paper.

RISK EVALUATION

Risk evaluation is an extension of the various systems of seriousness classification already widely used in industry.

In addition to the criticality of the consequences of bad workmanship the probability of occurrence of such bad workmanship is also taken into account. The result of criticality multiplied by its probability defines the predicted risk. In the statistics of high frequency events such as road accidents this result represents the average expected damage per event.

The two factors criticality and probability of bad workmanship define an area which is shown in matrix-form in Fig. 1.

The risk increases from a minimum in the upper left to a maximum in the lower right corner.

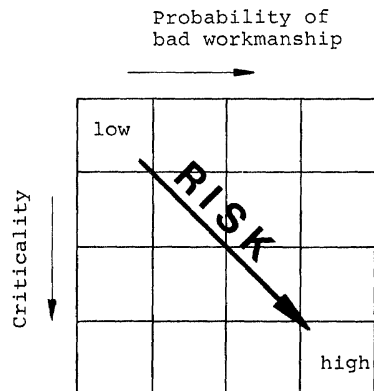


Figure 1 Risk Matrix

Based on our conviction that risk evaluation is an excellent management tool to define priority for the inspection function, all work orders have to be systematically evaluated. This means in practice an evaluation of each individual task line on each job card, to predict the risk involved. As an example all possible maintenance activities on a JT8D Jet Engine required a total of 6000 items for evaluation.

Criticality Classification

In the past aircraft design has been less complicated, maintenance organizations have been smaller and the ground mechanics had a direct contact with the flight crew (= user). A mechanic was often responsible for servicing "his" aircraft, for daily maintenance and overhaul, structure, components and powerplant.

Nowadays not only have aircraft become complex systems but also the maintenance organizations that go with them. Dozens of handbooks contain technical description and organizational procedures. Because a lot of specialists lack complete knowledge of the user system it has become more difficult to place any emphasis on inspection priorities. In an aircraft maintenance organization it therefore seems to be necessary to establish a committee for the criticality classification. As an example the specialists of the component workshops had to sit together with those of the aircraft systems-overhaul and daily maintenance. In addition, Quality Assurance took part in order to see to it that all committees applied the same standard for different types of aircraft as well as for electrical/electronic and mechanical systems.

To achieve the quality objectives required by the management the possible results of bad workmanship were classified - similar to Critical, Major and Minor - into the following 4 groups:

- A
 - No or insignificant consequences
 - No influence on operation or durability
- B
 - Adversely affecting operation without consequential damages
 - Detectable by flight-crew without adversely affecting flight safety
 - Detectable by inspection on ground with or without consequential damage
- C
 - Adversely affecting or precluding safe operation
 - Major consequential damages if no corrective action is applied
 - Examples: rejected take-off, flight interruption
- D
 - Hazardous or unsafe condition affecting flight attitude or individuals if corrective action cannot be applied
 - Endangering human life

Probability of bad Workmanship

No statistical material is available for the determination of the probability of bad workmanship. Consequently a practical approach to that end was therefore made based on the hypothesis that the probability of bad workmanship will diminish the better the resources of men, methods, machines and material become.

The "human" sources of error are composed partially of such elements as lack of basic knowledge, skill and proficiency. It is the responsibility of the employer to provide adequate training. In addition personality-related attributes such as attentiveness, power of concentration, reliability and care are even more important for the performance of high quality work. But since these attributes may only be improved by great efforts over a long period of time it is better to include such criteria in the personnel selection before employment.

The human influence factor cannot be evaluated in advance because the individual performing a specified job is not known. The standard of the resource element "men" is simply considered as "good" for the probability evaluation. It is then up to the supervisor who assigns a particular workorder to assess the individual and adjust the standard criteria as necessary. This means John Doe who has not yet completed all his training for a new type of aircraft will be classified as "poor" instead of "good" by his supervisor.

Therefore only the technical sources of error are considered in the planning stage for predicting the probability of bad workmanship.

An evaluation of "methods" centers around the degree to which orders are sufficiently detailed and understandable. In addition the degree of difficulty of the work process is to be considered. It is amazing how practical workers seem to be provided with a sort of instinct for classifying of their working methods into 4 categories.

"Machines" include all tooling and equipment required to perform the work. The main criteria is the degree of difficulty in its use or operating. Nothing can go wrong with a foolproof set-up. It is obviously more difficult if measurements, adjustments or switchings are to be made. In order to standardize the evaluation a classification of special tools and electrical/electronic test equipment was developed.

As to "material", its properties will give an indication of the degree of difficulty involved in its handling. Titanium for example requires the adherence to special procedures for the use of machine or hand tools. In a similar sense corrosion-, crack- or fatigue-proneness will influence the evaluation of maintenance work on aircraft structures.

The evaluation is carried out with the aid of an auxiliary table shown in Fig. 2. For practical purposes score values of 2, 4, 8, 16 are assigned to the classification and summarized to determine the probability of bad workmanship.

Resources	Criteria	Score			
		2	4	8	16
Men	Qualification	good	average	poor	very poor
Methodes	Degree of Difficulty	easy	average	difficult	very difficult
Machines	Operating Characteristics	easy	average	difficult	very difficult
Material	Handling Properties	easy	average	difficult	very difficult

	Score Total			
	8-10	11-20	21-40	41-64
Probability of bad workmanship	very unprobable	little probable	fairly probable	probable

Figure 2 Table to establish probability of bad workmanship

Evaluation example:

			Score
Men	:	good	2
Method	:	difficult	8
Machine	:	average	4
Material	:	easy	2
			<hr/>
Total			16 "little probable"

If John Doe with his personal qualification "poor" and corresponding score of 8 is assigned to this job, the total score is 22 and the probability of bad workmanship moves up to "fairly probable".

SPECIFICATION OF INSPECTION FUNCTION

After the technical experts have determined the risk, it is up to the management to decide its acceptable level. Beside the risk/cost analysis the difference in public reaction to an event with 100 fatalities (airplane crash) and 100 events with 1 fatality (road accidents) has to be considered. This phenomenon is called "risk aversion" in the decision theory.

In SWISSAIR we use the following 3 inspection procedures:

The basis for achieving high quality work is the concept of self-control, which is applied as a general principle to all tasks regardless of their risk classification. That means that each individual has to reread his workorder and check that all required work has been performed, all procedures adhered to. This may even include an actual inspection. Only when this process of mental checking is concluded each individual task is properly signed out by the worker who performed it.

Tasks where bad workmanship may endanger human life or adversely affect the safe operation with an at least fair probability must be inspected through an independent double check. This inspection must be carried out by an appropriately trained individual who has no authority to give any workorders for this particular task nor take any part in performing it. It is thus a completely independent inspection function.

There is an intermediate inspection stage for tasks where bad performance may adversely affect the safe operation with low probability or high probability but detectable by the flight crew. This type of double check can be carried out by appropriately trained individuals who may be member of the team but are not allowed to check their own work.

For practical purposes the specified double checks and independent double checks are listed in an inspection catalogue. If necessary this catalogue will be revised twice a year by the same team who originally established it.

These inspection functions are superimposed on the risk evaluation matrix as shown in Fig. 3. With this method a clear relation is established between the evaluated risk and the inspection function.

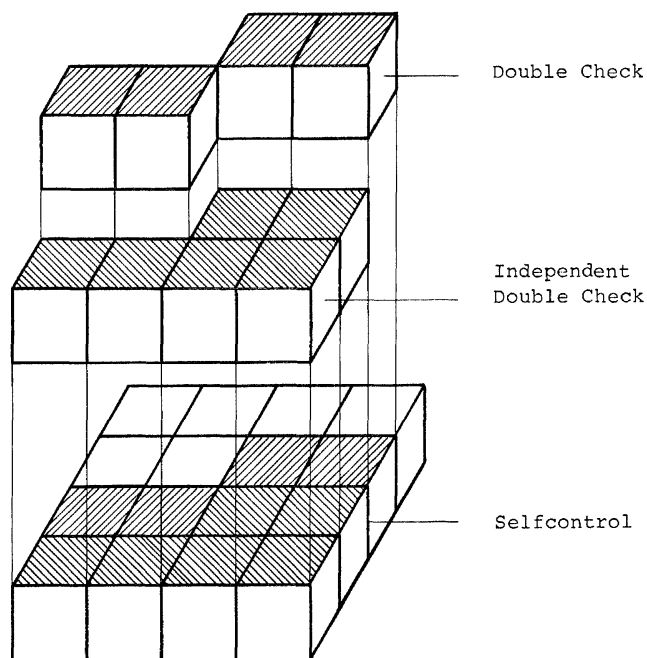


Figure 3 Specification of the Inspection Function to the Risk Matrix based on selfcontrol for each individual task with superimposed double checks or independent double checks

CONCLUSION

RISK EVALUATION is an effective management tool because it provides a systematic approach to specifying the inspection function. Key-points in the inspection effort are established largely independent of individuals. The classification of inspection function is well balanced over a whole range of activities because the decisions are permanently compared with each other during the evaluation. Even an open discussion about risk evaluation and specification of the inspection function will result in a quality improvement.

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LCS 342: 10 : 545

QUALITY CONTROL AND DATA BASE MANAGEMENT SYSTEMS

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As computer data bases replace conventional paper work and microfilm systems, the need for computer data base quality becomes extremely important. Imagine your reaction should a computer call you to active duty as a combat fighter only to find that you were 60 years old, and retired. Or suppose you were a captain in the reserves who had superior ratings on your last five efficiency ratings with four commendations and a presidential citation, and you missed being considered for promotion because of an error in the computer data base.

The Quality Analysis Branch at the Air Reserve Personnel Center is dedicated to help prevent these horror stories from becoming realities. The main tools at our disposal are:

- (1) Clerical checks of Personnel Records vs the computer data base.
- (2) Quality audits of the clerical effort to ensure that quality standards are being met.
- (3) Local computer edits to ensure that clerks are not entering impossible or improbable data into the data base.
- (4) Central computer, in-depth edits screening data going into the master data base.
- (5) System edits or purges to verify the quality of information already in the data base.
- (6) Clerical error correction.
- (7) Computerized error correction.

Data on reserve personnel normally flows into our data base from other computers or from other files stored in our computer by other agencies. As an example, when an airman serves his active duty tour and transfers to the Reserves, his personnel data is transferred from the Active Military Service File to the Reserve File. Errors may have been in the file before the transfer, and errors may be created by the transfer.

In order to have a reliable data base, it is necessary for the incoming data to be reliable. That is why clerks check the quality, and Quality Analysis checks the clerks. Quality Analysis also reviews the need for both clerical checks and quality audits on a monthly basis. When a specific data element flowing into the Reserve Data Base is shown to be above the quality standard for a 3-month period, Quality Analysis recommends that the data element be dropped from the routine clerical review process. When the overall quality of clerically reviewed records is better than the quality standard, Quality Analysis stops routine audits for the Branch involved. Random follow-up audits will be scheduled in 6-12 months, unless routine data base audits show that the quality of the data items monitored by that Branch has degraded.

Local computer edits are generally quite superficial, but they do give prompt response to the clerk inputting data or corrections via the computer terminal. Typical rejections at this point would be for trying to enter a letter where only number entries will fit. The simplicity of these edits is due to the limited capability of the prescreening hardware. Their greatest value is that they let the clerk know of the error immediately, and thereby contribute to the clerk's training.

The central computer makes more complex edits of the data before updating the data base. Typical screens would include requiring that nonexistent codes are not listed in the files. Another check would be to ensure that the date of transfer to the Reserves is not greater than the current date.

Manual and computerized system edits are run to ensure that the systems are working properly. The manual edits are slow but thorough. As a consequence, they are used to audit critical data or to trouble shoot system problems. A typical manual edit would be the evaluation promotion data items on full colonels prior to a General's Promotion Board. Another typical manual edit would be evaluation of the quality of Mobilization data items prior to a mobilization test. Manual edits involve reviewing the computer data base information on those data items against the Master Personnel Record. Since manual edits on Mobilization Data items average over a half hour per record, the sample size is normally small.

Computerized edits are much cheaper and less time consuming, but the resultant data is seldom as accurate. Systems used in the computerized edits are quite similar to those used with incoming data. As an example, the edit may require that the year a Reservist finished school must not be later than the year of the edit. Another example, would be an interrelationship requiring that a Reservist's address should not be unknown unless that Reservist's address status is also unknown.

Computerized edits can be misleading. An edit of when a Reservist was last promoted may show 100% quality if the only criteria is that the data base show something other than unknowns. Entries claiming that the Reservist was last promoted in 1904 or 1984 would both be accepted as good data. The key to having an effective computerized edit is to have criteria that detect all impossible data. Improbable criteria should also be eliminated where the data is important and where computer programming skills and adequate knowledge of the proper screening criteria exists. An example might be the permanent grade of an officer. This data item is shown numerically where 01 is a second lieutenant, and 03 is a captain. Numbers 21-24 are reserved for warrant officers. This edit could easily require that this data item be between 01 and 10 or between 21 and 24. This screen detects all alphabetical or impossible codes for an officer's grade. The edit could also include a requirement to spot all generals under 40, all colonels under 35, etc. There could be a general under 40 and there could be a colonel under 35, but the probability is low enough that their records should be given a thorough manual edit.

Statistical techniques are quite valuable in detecting probable errors that deserve further review. As an example, it is easy to statistically determine the average and standard deviation (σ) for the number of retirement points a reservist will have after qualifying for retirement at age 60. The record of anyone having less than the mean minus 3σ points or more than the mean plus 3σ points should be thoroughly reviewed. It is relatively easy to have the computer screen 80,000 records against these criteria.

A correlation of age versus grade could also be used to detect probable errors in the data base.

ERROR CORRECTION

The importance of a data item has a critical impact on how that item will be edited if it is to be edited at all. Reservist address, as an example, is critical. If we do not know how to contact that reservist, his other statistics are of little value to the system.

The impact of an error is also important when it comes to the number of retirement points accrued. It is more hazardous to shortchange a 20-year Reservist who is about to retire than one who is about to complete his obligation to the Reserves. There is no doubt that the retirement points will influence the 20-year Reservist's retirement pay whereas the short term Reservist may drop out of sight as soon as his obligation is met.

Other variables having an influence on how or whether a data item should be edited include the economic impact of the error (Reference 1), the quality of the data item, and the difficulty of correcting the error. Why spend \$10.00 correcting the data item when the potential savings to either the government or the Reservist will never exceed 10¢. This may be a direct saving as in retirement benefits, or it may be indirect based on its effect on the Reservist or the mission of the Air Reserve Personnel Center.

A corrective action effort is normally initiated when the quality of a data item drops significantly below 95%. The first question is "Do we have a systems error?" System errors are most common with data created or changed by the computer when new records flow into the data base. Computer programs have been developed to identify the frequency of the error and even the approximate time that it surfaced. Time of occurrence is of value to the systems analysts since system errors are normally associated with programming changes. A good computer program is not likely to go bad unless someone does something to it. In most cases the programmers were correcting another error or "improving" the system. By knowing when the error started to occur, the programmers will have a good idea on where to look for the offending change in the system.

When the errors are critical, and not correctable by the computer, the slow and tedious processes of manually correcting the records becomes necessary. This is where the cost vs benefits evaluation comes into play.

When the errors are minor or computer generated, a computerized approach is considered. Methods used by the census bureau (Reference 2) such as cold deck, hot deck, and Monte Carlo corrections are of little value to the Reserve Center. The census bureau is working with masses of statistical data and is interested in statistical conclusions whereas the Air Reserve Center is primarily involved with specific data effecting specific individuals.

Automatic computer corrections are most effective in our records when a systems error has been detected. One example was where a specific data element showed zeros where zero was not of an assigned code. The error was generated when data came into the local system. In these cases computerized corrections are relatively simple. Computer programs can be written to locate all of the zeros in that specific data element and change them to the proper code. However, had this not been a systems problem, the corrections would be much more complex. We would perform extensive manual audits to ensure that all of the zeros should have been another single code, and then make the change--if appropriate. If there were more than one correct code for the zeros more complex analysis would be required. For example, a 6 in the code in question may correlate perfectly with a 37 in another data element shown in the same reservist's record. When this occurs, computerized corrections are still feasible.

Other possible applications for computerized data correction (which we do not use) include:

- (1) If a month is shown to be over 12, change it to a 6. You can't be more than 6 months off.
- (2) If a day is shown as over 31, change it to a 15. You can't be more than 16 days off.
- (3) If sex is unknown, call the reservist male since the population in the Reserves is primarily male.
- (4) If 2 data items should correlate, but don't, assume that the data item with the least number of possible codes is correct. As an example favor numeric codes over alphanumeric codes (Reference 3).

PROBLEMS WITH AUTOMATED CORRECTIONS

One of the biggest risks in automated data correction is that the corrections frequently create errors that are much more difficult to detect than the original error. It is easy to spot August 52, 1970 as being in error, but it is much more difficult to spot August 15, 1970 as being in error when the correct date is August 1, 1970. Chances are about 30 to 1 that a computer generated August 15, 1970 is not the correct date. In most of our records this type of approximation is not acceptable, although it might be perfectly all right for a census analysis.

A good rule of thumb would be to limit automatic or computerized data correction to errors created by the computer, or areas where the resultant errors will not cause serious repercussions. You don't want to insult a woman by assuming that she is male, just because blind statistics favor that conclusion.

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MANAGEMENT'S ROLE IN THE QUALITY ASSURANCE FUNCTION

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In fiscal year 1978, the Social Security Administration will authorize payment of more than 96 billion dollars in cash benefits to more than 35 million people receiving retirement, survivors, and disability insurance benefits and supplemental security income benefits. Administering programs of such magnitude, affecting so many lives, is an awesome responsibility and requires extreme sophistication.

Being a public program, it is necessarily subject to public scrutiny. Members of the Congress and the press and everyone who has ever paid social security taxes or who receives or can expect to receive benefits has a personal interest in these programs and how they are managed. As you know, this past year there has been somewhat more public interest in financing the retirement, survivors and disability insurance programs, than in the efficiency with which they are run. Nonetheless, the very size of our operation has caused increasing attention to be given to how well we are managing our trust and what we can do to improve our management.

This afternoon, I will outline some of the problems of program measurement inherent in SSA. I will explain the nature of our programs and their major characteristics and objectives. Then I will explain the nature of the system we're designing to measure how well we're doing in meeting our objectives and how we intend to plan and initiate corrective actions for those areas we find deficient.

The Social Security Act and amendments to it establish a number of programs which have the objectives of providing some protection for retired and disabled workers, their families and survivors of deceased workers, protecting aged and disabled persons against health care expenses that could otherwise exhaust their savings, keeping families together, and giving children the opportunity to grow up in health and security. These programs include: retirement and survivors insurance, disability insurance, health insurance (better known as Medicare), supplemental security income for the aged, blind, and disabled (SSI), unemployment compensation, Aid to Families with Dependent Children, and Medical Assistance for the needy (better known as Medicaid), among others. The Federal Government operates the retirement, survivors, and disability insurance, Medicare, and the SSI programs. The other programs are operated by the States with Federal cooperation.

Today, I will concern myself mainly with the retirement, survivors and disability insurance programs, which account for nearly 93% of the projected \$96 billion I referred to earlier. Payments under these programs are commonly known as social security benefits. These benefits ordinarily are paid by check directly to the beneficiary, and are thus referred to as "cash benefits" to distinguish them from Medicare benefits which are generally paid on a beneficiary's behalf to the person or organization that furnished health care services.

Monthly social security cash benefits can be paid to: a disabled insured worker under age 65; a retired insured worker at age 62 or over; and to the spouse or dependent child of an insured retired, disabled, or deceased worker under certain circumstances.

By way of example, for November 1977, the retirement and survivors insurance program (RSI) paid out nearly \$6½ billion and the disability insurance program (DI) paid about \$1 billion.

A prime objective of the Social Security Administration is to get the right check to the right person at the right time. To further this goal, the Office of Quality Assurance (OQA) is charged with determining the extent to which SSA policies and procedures support that objective. To accomplish this, OQA is designing and will administer a sample review system for the RSI and DI programs. This system will be similar in many respects to the system we have been operating for SSI since 1974.

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We are planning on initiating the RSI and DI reviews when the next fiscal year starts, in October 1978.

Our review data will be tabulated and evaluated so that we can report on program quality and develop recommendations concerning improvements in program operations. The objective of our reporting system is to assure that top management is regularly provided with valid and timely information which it needs about program quality.

As you can well imagine, failure of beneficiaries to receive their checks promptly and in the correct amounts can result in considerable hardship. However, unlike the situation which prevails in industry, the government does not risk the loss of a customer and future sales for lack of quality. For better or worse, the beneficiary can't take his business elsewhere. Thus, the loss to the beneficiary resulting from substandard government service on which he is forced to rely cannot be measured in terms of dollars alone, but must also be considered in terms of humanitarian needs. But that's a two-way street. If SSA, for example, doesn't pay the right amount at the right time to the right person, it can be the beneficiary's fault in circumstances where he or she was required to make a report but failed to do so. Thus, the review system which we design must include the capability of allocating responsibility for failure to meet the program objective. Without such an allocation, we would be faced with error rates with significant hidden components for which management would have little hope of effecting reductions.

For the retirement, survivors and disability insurance programs, we are designing four primary samples, each of which covers a six-month period. For cases in payment status, 6,000 retirement cases will be selected, and 6,000 disability cases will be selected. For cases not in payment status--that is, situations in which benefits are suspended, terminated or applications are disallowed 2,000 cases for each six-month period will be selected from each of the two programs. Thus, each month, a thousand payment cases, and a third that many nonpayment cases, will be randomly chosen from each of the two programs. These cases are identified from our Master Beneficiary Record. This Record contains a list of all persons receiving benefits, or who have received benefits in the recent past.

The number of cases to be selected for the payment sample was originally designed to be large enough to give precision limits of plus or minus one percent at the ninety-five percent confidence level, while allowing for some exclusions which will not bias the sample. However, this would have required less than 2,000 cases. Given the large variety of reasons why payments can be incorrect in our programs, we considered it necessary to increase the sample size substantially so that our tabulations would distribute the causes for such incorrect payments in such a way that trends and concentrations of problems would show up clearly. Only in this way would we have the basis for initiating special studies for intensive evaluation of problems uncovered by our findings or for planning corrective actions. Thus, the sample is about 3 times what is expected to be needed to meet reliability specifications. Moreover, if our assumptions concerning projected payment discrepancy rates are too low--and this is possible because we have no precedent in the RSI or DI programs for across-the-rolls estimates of such rates--we will still meet the desired reliability criteria.

Cases will be selected and reviewed on an account basis. This means that the family benefit amount based on the earnings record of the individual whose social security number is sampled, will be reviewed for accuracy.

The major indicators of program quality which OQA will measure in its sample review system are the accuracy of payments (that is, the proportion and amount of dollars overpaid and underpaid), and the accuracy of negative case decisions which include disallowances of new claims and suspensions and terminations of claims previously paid.

Information related to the accuracy of payments and accuracy of nonpayment decisions will be categorized in terms of whether a deficiency originates in a process controllable by SSA. For example, an administrative deficiency may result from an incorrect arithmetic computation of benefits. An uncontrollable deficiency is defined to be one over which SSA had little or no control. Ordinarily, this would occur when a beneficiary fails to report a change in circumstances as required.

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Reviews of sampled cases will be of two kinds: desk reviews and field reviews. The desk reviews will be conducted in our 10 QA Regional Offices, and the field reviews will originate in our 27 field offices, which service the 50 States and the District of Columbia.

When a case is sampled, the claims folder will be requested automatically. RSI claims folders are stored in 6 Program Service Centers, located in New York City, Philadelphia, Birmingham, Chicago, Kansas City, and San Francisco. Most DI claims folders are stored in Baltimore. For both programs, some inactive claims folders are stored in Federal Records Centers, but are retrievable when needed.

The content of the claims folders ordinarily include the original applications for benefits, evidence to support the applications (such as proofs of age, marriage, and death), and a certified copy of the insured individual's record of earnings covered by social security. It also includes a history of payments, adjustments, suspensions, and termination actions for the claim. In addition to the claims folder, the desk review will also require review of a printed summary of the Master Beneficiary Record and other documentation which may be available in SSA's files. The review of these documents will constitute the desk review, the findings of which will be summarized, coded, and input through SSA's nationwide computer system into OQA's special data base.

Concurrently, the printed computer summary will be sent to the OQA field office servicing the address of the sampled beneficiary. It will be used as the basis for determining whether the criteria are met for initiating contact with the beneficiary and how such contact should be made. For example, it may not be cost-effective for us to visit a 78 year old retired worker since the visit, per se, could not serve to provide entitlement data which we could not obtain from our files. An alternative might be to send a letter asking him to verify whether and when he received his check for the sample month, and the amount of the check. This would serve to verify that our system accurately reflects his status.

If a field visit is appropriate, usual survey techniques will be employed. That is, all beneficiaries entitled on the sampled earnings record will be notified of when we plan to visit and requested to have certain information and/or documentation available when our representative visits. An acknowledgement notice will be included for postage-free response.

If information collected from the beneficiaries is not sufficiently documented, we will undertake contacts with collateral sources of evidence. For example, if the beneficiary does not have a copy of his/her marriage certificate, we might contact the custodian of the public record to obtain verification of the marriage.

Upon completion of data collection in the field reviews, the findings will be summarized, coded, and input to the central office computer in the same way as described for desk reviews. Should findings of the two types of reviews disagree, an exception process will alert us to the fact. We believe that the way in which the system is being developed will minimize the frequency of such occurrences. But when they occur, we will associate the findings from the separate segments of the review and undertake a reconciliation.

We must deal with large numbers of claims folders--millions of pieces of paper--whose movement should be minimal to exercise effective controls. We also have to keep travel expenses of reviewers down. Thus, we have developed the split review approach which has just been described. We recognize that there would be advantages to having one person do the complete review, but cost effectiveness issues had to be considered, and this became another example of how management plays a role in the development and operation of a quality assurance function.

As noted earlier, our primary samples will be supplemented by special studies. These will encompass three broad areas of interest. First, there will be intensive studies of areas which our basic findings highlight as problems or potential problems. An example might be a situation in which we find that we have an unusually large proportion of incorrect payments to children, but no clear delineation of the causes. Since there are several categories of children's benefits, we could select a fairly large, stratified sample as a special study to pin down where the problem is. This would be a logical outgrowth of our ongoing primary study findings. In fact we are

so convinced that the payoff for quality measurement is in corrective action that half of the resources available to us have been committed to special studies.

A second area would be periodic special studies to monitor areas which cannot be measured with precision in the primary samples. For example, the nature of the social security annual earnings test (that is, the limit on earnings of beneficiaries under age 72 before they start to lose benefits) is such that it can't be reviewed during the year; it can only be evaluated after the close of the year. Thus, for us to measure the effectiveness of both SSA's administration of the test and beneficiary compliance with reporting requirements under the test, we will probably conduct routine annual special sample studies of it.

The third type of special study may be characterized as the ad hoc sample. This will represent unscheduled reviews into areas which are not normally the focus of our quality reviews; one-time studies, for the most part, which do not stem from findings of our primary samples. For example, there is a category of individuals age 72 or older who receive benefits even though they were not insured under social security. This was a temporary provision which, as a practical matter, doesn't permit additions to the rolls, whose average payments are very low, and whose benefits and cost of administration are reimbursed in full to the Old-Age and Survivors Insurance Trust Fund from the general funds of the Treasury. Because of the small and rapidly diminishing size of this group, it is impractical to include them in our primary samples. Should we see a special need to evaluate this group, an ad hoc sample study would most likely be the best approach.

The three types of special studies just described emphasize the role of management in quality assurance. They illustrate the wide variety of decision making opportunities which occur and are needed in the effective deployment of resources just to monitor the health of the programs which we administer.

Until now I have alluded only briefly to corrective action. But the whole focus of our system is to develop information on which plans for such action can be formulated. This is akin to an industrial quality control operation in which, for example, ball bearings are measured on a sample basis. If tolerances are exceeded, management must determine whether settings of tools must be adjusted or whether the manufacturing equipment needs replacement. Careful data collection will show what the appropriate remedy will be so that disruptions to both quantity and quality of production are minimized. Similarly, findings from our RSI and DI quality review samples, as with our presently operating SSI sample, will identify and categorize the nature and sources of deficiencies in our programs--with heavy emphasis on where and why overpayments and underpayments to beneficiaries are occurring.

I should note that consideration has been given to the consequences of the Social Security Administration not undertaking an across-the-rolls measurement of benefit payments. (Currently, we measure only a very small proportion of payments.) After all, this new system represents a major commitment of resources--several hundred full-time employees, extensive travel, and allocation of sophisticated computer equipment which, together, represent a substantial annual investment of funds. SSA's top management has concluded that it would be irresponsible to continue our operations without such a system. If we don't measure the accuracy with which we make all payments, we fail to meet basic management needs. We also fail to perfect our capacity to respond to requests for information which we are already receiving from the Congress and the press. We recognize that national resources are necessarily limited and that we invite avoidable unfavorable criticism by not proceeding quickly to both measure and improve the accuracy of payments we make. Moreover, we recognize the responsibility to develop a system which will not only be respected internally, but will pass the careful scrutiny of the Department's Audit Agency, the General Accounting Office, and others.

Should we fail to institute our program of measurement, we would obviously be unable to take appropriate corrective actions. Hence, we would be unable to meet our own objective of furnishing the level of service to the public which constitutes the best which can be provided with the funds available. The public and our own consciences combine to demand that we strive to achieve that objective with all the tools at our command. In SSA, quality assurance is one of those tools. But it requires continuous management attention to assure that it serves as an objective source of useful information. Without such attention it would, itself, become a misleading and wasteful element in our agency's operations.

310:10:991

EVALUATING THE QUALITY OF STATISTICS OF INCOME

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The recent wave of consumerism has resulted in an ever-increasing awareness of product reliability by both the producer and the user. The user demands and has a right to be informed about the reliability of an item whether it is a manufactured product, a service, or, as in our case, a published statistic of income. Since defects in statistics are much less likely to be detected by the user than in products or services, we are entrusted with a great responsibility to either publish perfect statistics or indicate their degree of reliability.

This paper describes the system we have designed and developed to enable us to evaluate the quality of the data contents of the computer file from which the published statistical tabulations are derived. The file is the end result of various data processing operations, including the manual abstraction of data from a sample of tax returns, transcription, consistency testing, weighting and error resolution.

A major function of the Statistics Division in the Internal Revenue Service is the publication of Statistics of Income (SOI). This is done basically by abstracting information from a sample of the tax returns filed by the taxpayers, transcribing it onto tape, subjecting it to consistency testing, processing it through error resolution, weighting it, and publishing the resultant data.

It can readily be understood that quality control in published statistics is more difficult to appreciate than in a manufactured product. Quality control in a color TV set, for example, can easily be determined by the consumer by such simple questions as: Does the picture come on? Is there sound? Is the color satisfactory? Do all the different control knobs work? Does the set operate properly for an expected period of time? Realizing that a consumer can generally determine the quality and reliability of a product once he purchases it and that he will complain and request redress if not satisfied, the manufacturer builds in a certain degree of quality and reliability. He carefully weighs the costs of loss of good will, refunds, exchanges, and possible recall if there are quality problems against the costs involved in a quality control program to prevent such problems. He will then choose an optimum processing plan that will in the long run produce the best financial return for his company. Similar conditions prevail in the quality control and reliability aspects involving services provided to a customer, such as repairs and legal, financial, medical, business and government services.

In published statistics, however, the picture is different. The user of the data can often not readily recognize good or poor quality. He cannot, as with a manufactured item, determine if a numerical value works or doesn't work. He cannot tell if a million dollar figure is off by a dollar, ten, a hundred, or even a thousand dollars. Experience has shown that users will detect format errors in tabular presentations such as erroneous columnar headings, stub items, etc., and also figures that do not fit into a pattern. But generally they will not detect errors in figures within a table unless they specifically analyze a certain figure in detail, utilizing various other related sources of information, and are very knowledgeable in the field dealt with by the item.

This situation puts us into a very unusual situation. Why have comprehensive quality control when the results are often not recognizable? It is a matter of trust and confidence by the user. The user, except for the stated sampling error, expects the data to be completely reliable and we have an obligation to provide reliable data. Further, we should be able to inform the user about the degree of reliability we are providing him.

We have taken many steps to control the quality of the data we publish, emphasizing the areas where errors are most likely to occur and where they have the best chance of being corrected properly. However, we are still not able to, with sufficient confidence, tell the user how reliable the data are that we are providing to him. This paper will deal with what we are currently doing to bridge that gap.

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Following is a brief summary of the processing operations involved in the preparation of Statistics of Income. Individual income tax returns (Forms 1040) will be used in the example although we compile and publish similar statistics for corporation, business, gift, estate and fiduciary returns, some on a yearly and some on a more infrequent time basis.

Through discussions with users of income tax data, such as government agencies who use these data for economic and fiscal planning and development, our Division determines what information is to be extracted from income tax returns. Instructions and procedures are then prepared for the abstraction of the information. This includes the preparation of an edit sheet (abstract sheet), editing instructions to direct how to abstract the information, and various other instructions such as sampling, controlling, quality control, shipping, consistency testing and error resolution.

Of the 130,000,000 tax returns filed during the year, about 360,000 are randomly sampled for the various Statistics of Income programs. The Individual sample involves about 200,000 out of the nearly 90,000,000 tax returns filed. This includes business, nonbusiness and farm returns. The 1040 returns are filed at 10 Internal Revenue Service Centers throughout the country and this is where the SOI sample is also processed.

Abstracting of tax return data for SOI is performed immediately following the revenue processing of the returns. (Revenue processing is the service center review for mathematical accuracy and compliance with the Internal Revenue Code.) Utilizing our various Internal Revenue Manual instructions, the SOI returns, which have been computer-sampled earlier, are pulled, edited, verified and transcribed onto tape. Subsequent to this, the on-tape SOI data from all 10 processing centers are forwarded to the IRS Data Center in Detroit and subjected to consistency testing. Inconsistencies are either corrected automatically internally or through manual error resolution. Then the data are weighted, consolidated and statistical tables are produced, reviewed and published in the form of SOI reports with accompanying descriptive narrative.

The quality of the statistics has always played a large role in the SOI processing operation. However, our main thrust of quality review and quality measurement has been in the editing phase. Originally it consisted of 100 percent review of all data and it subsequently led to 100 percent review of critical areas of the data, lot-by-lot acceptance sampling, and continuous sampling verification. Assuming, and we think properly so, that the most critical area of quality emphasis should be when the data are first abstracted, we are currently using a fairly comprehensive quality control program for this phase. It is a two-pronged operation: one involves an inprocess review of the edit sheets by people within the editing unit, utilizing a continuous dependent verification plan; the other involves an independent review in the Statistics Division of a subsample of the edit sheets prepared in the field. Both reviews operate on the same basic premise, that an edit sheet wherein one or more items are abstracted incorrectly (excluding errors within designated tolerances) is considered defective.

Edit verification is intended to control the quality. The assignment of a specific "i" value (clearance number) and "f" value (sampling frequency after an "i" number of consecutive edit sheets have been found to be defect-free) to a specific category and type of document (e.g., 1040 Nonbusiness Small) assures that the percent defective edit sheets will not exceed a certain "Average Outgoing Quality Limit."

The independent review of a small subsample of the SOI edit sheets is intended to measure the actual outgoing quality of the edit sheets in addition to detecting errors caused through inadequate instructions. It provides feedback to the processing centers on error data thus allowing for subsequent upgrading and ensuring uniformity of instruction utilization among the processing centers.

It appears evident that the quality of the editing phase of SOI processing is fairly well covered. However, the SOI data, as pointed out earlier, is subjected to several additional processing stages: transcription onto tape and consistency testing/error resolution. Although quality control measures are applied to these subsequent operations they are mainly for review, not for measurement. For example, in transcription, each edit sheet is retranscribed by a key-verifier and any non-matching entries are supposedly resolved. Studies however have indicated that this review plan, though seemingly infallible, has allowed some error conditions to remain present or even introduced additional ones. For example, a key-verifier with his power

to override an original entry can erroneously introduce an error, inadvertently retain an original entry error by keying in the same error, or can purposely retain an original entry error by arbitrarily failing to correct it. The true extent of these error conditions is currently unknown although the service centers in their Service Center Quality Review System have established that this problem does exist.

In the consistency test/error resolution phase of the SOI processing operation, errors again may not be detected or may even be introduced. Consistency testing is limited in scope to items that lend themselves to this type of check. If an item or a combination of items fail a certain test, it generally means that an error condition is present. During error resolution, corrections are made to one or more items to render the data on an edit sheet as a whole consistent. This is often done without the benefit of the tax return. Possibilities of incorrect "corrections" are thus present. Small studies in this area have borne this out. Again, as with transcription error, we do not know the extent of this type of error.

In summary, although a fairly reliable estimate of the data quality is available for the editing phase, we recognize that the quality of the final published data may not portray the editing quality because of errors introduced and/or corrected in subsequent phases of the SOI processing operation. We feel that the user of our data has a right to be informed about the quality of the data we are providing to him and that we have a responsibility to provide him with this information. Although we feel our data are fairly reliable, we want to be able to back it up with statistical data.

To establish the reliability of our published data, we developed and implemented a project last year called the SOI Data Reliability Project (or Study). Initially, we are implementing the Reliability Project on the three major SOI programs, the Individual, Corporation, and Partnership programs.

Basically, the Reliability Study is an extension of the existing Quality Assurance procedures. As was pointed out earlier, we currently measure the quality of the abstracting by independently reviewing a randomly selected subsample of the returns that are edited. This Quality Assurance subsample for the Individual Income tax returns involves approximately 2% of the SOI sample. There are three main categories of returns included in the SOI program: nonbusiness, business, and farm. The Quality Assurance subsample comprises a different percentage of returns from each of these categories, determined by the size of the SOI population in each category.

The evaluation of the final quality, the computer file used to produce tables for publication, will utilize the same Quality Assurance subsample and follow it through the various post-editing processing stages. Since all of the post-editing data are on tape, we will utilize the computer as much as possible to aid us in the detection of errors and subsequent evaluation.

The Reliability Study entails various operations subsequent to the Quality Assurance processing. First, we will retain all of the Quality Assurance edit sheets and copies of those tax returns for which the corresponding edit sheets were found to be in error during Quality Assurance review. In order to determine what happened to the edit sheet data subsequent to editing, we have requested two basic computer printouts for each Quality Assurance edit sheet, one following the transcription of edit sheet data onto tape and the other following the resolution of errors read out in consistency testing. For transcription and consistency-tested documents that differ from the Quality Assurance edit sheets, we will obtain copies of the corresponding tax returns. We are also requesting several additional computer printouts that will facilitate our analysis and evaluation. These include, for both the transcription and the consistency-tested files, summary listings for all Quality Assurance records of aggregate dollar amounts on a cell-by-cell (item-by-item) basis for all money items and aggregate frequency of occurrence counts on a cell-by-cell basis for all code and money items. In addition we will match the transcription file against the consistency-tested file for all Quality Assurance documents and obtain a listing of all consistency-tested records that differ on a cell-by-cell comparison of both edit sheet code values and dollar amounts (within a tolerance of \pm \$25 for dollar amounts) with the matching transcription record.

Through the utilization of the various computer records and the filed Quality Assurance edit sheets and tax returns, we will analyze and evaluate the error data in the various stages of SOI processing and eventually determine the reliability of the final computer file. We will compare the transcription data to the edit sheet and determine the differences. Both the frequency and dollar magnitude of the transcrip-

tion errors will thus be determined. We will then analyze the mismatched items from the comparison of the transcription file with the consistency-tested file. If the consistency-tested file contains differences other than errors detected during Quality Assurance processing and errors made during transcription, the tax return will be consulted to determine if the consistency-tested item is consistent with the tax return data. If not, it will be considered a consistency test error. At this stage we will determine the error rate of the consistency-tested file. In determining whether the consistency-tested item reflects the correct tax return data, proper consideration will be given to possibilities of taxpayer errors. Subject matter specialists throughout the Division may be consulted in making this determination.

Once all of this evaluating and analyzing has been performed, we will be able to indicate the reliability of the computer file, i.e., the number of SOI edit sheets in error, the number of individual cells in error, and the dollar magnitude of the errors on a cell-by-cell basis. The prime final error rate of the computer file, the percent of documents defective, will be determined as follows:

- Percent defective of Quality Assurance edit sheet records
- + Percent defective of the transcription records (excluding those also QA % defective)
- + Percent defective of the consistency-tested records (excluding those also QA or transcription % defective)
- Percent of records corrected in consistency testing/error resolution

The reliability data will be weighted based on the Quality Assurance subsample sizes of the various SOI return categories and the sample limitations will be indicated.

Results of the Reliability Study, in addition to informing us of the reliability of the computer file, will show us at which stages errors are introduced during SOI processing, how significant they are and if, when, how, and to what degree they are corrected in subsequent processing stages. This information will enable us to determine what additional if any quality control measures should be applied to the post-editing processing of SOI. If the error rates are acceptably low, we will not make any substantial changes. If not, we will determine where and how to take corrective action. Quality emphasis and resources can be redirected from editing to transcription or to consistency testing/error resolution to achieve the most reliable product with the given resources.

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SPARE PARTS PROVISIONING ANALYSIS FOR POWER PLANTS

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ABSTRACT

The purpose of this paper is to provide a recommended analytical approach to the identification of each spare and replacement part or material and to the determination of an appropriate initial procurement quantity for each spare and replacement part or material. The paper describes problems which have been encountered in attempts to identify and quantify spares and correspondingly provides proposed solutions to these problems. The paper also describes each of the factors which should be considered in the analysis.

INTRODUCTION

In performing a spare and replacement parts provisioning analysis for a power plant, the analytical process can be divided into four categories--namely, (1) the identification of each spare and replacement part or material; (2) based on some statistical estimating technique, the determination of a best estimate quantity for each of these parts and materials; (3) the adjustment to the best estimate quantity based on nonstatistical factors; and, (4) the determination of quantities for special reserves to accommodate unusual circumstances. This paper is organized along the lines of these four categories. In addition, a recommended spare and replacement parts provisioning analysis form, which follows the steps in the analytical process, is provided as Appendix 1 to this paper with the instructions for completing the form provided as Appendix 2.

It must be emphasized that at the time of this writing we have had no conclusive, long-term experience with this analytical process. However, we have recognized the need for improving the existing spares provisioning process and we have had extensive discussions on this recommended approach. We have incorporated this approach into our Request For Proposal for our Spare and Replacement Parts Provisioning Program for the Midland nuclear plants. It might be appropriate, therefore, if the experience with this analytical approach were reported at some future meeting in a year or two at which time we should be able to determine its degree of success as well as to identify its needed refinements.

Parts Identification

The analysis must start with the identification, on a line-item by line-item basis, of each spare part, replacement part and bulk material which will be used for replenishment. A spare part or a replacement part is one which will perform the same function as did the original part. However, a spare part is capable of being installed without any physical adjustment, whereas the installation of the replacement part is dependent upon some physical adjustment to the part. For a power plant there are probably few replacement parts, whereas for other complex products, which are produced in quantity and serviced in the field, there may be many replacement parts. An example of a replacement part might be a wing skin panel for an airplane. The panel would probably have to be drilled or shimmed or filed to fit in the field when it is used to replace the existing skin panel.

There is no universally established way of assuring that each spare or replacement part or bulk replenishment material is identified, but an appropriate way would be to require that the preparation of a spare and replacement parts or materials list be part of the original design work scope and that each drawing be released with its corresponding spare or replacement parts or materials list (different from the "bill of materials"). This makes sense in view of the fact that during the design process the designer is most intimately familiar with his design and it is during this time that the designer must take into account the spares impact on maintenance and maintainability. During the design process the amount of engineering man-hours required to establish the spare or replacement parts or materials list is the least. In addition, providing the spare and replacement parts or materials list at this time

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significantly minimizing the risk of having to perform the spares identification, quantification and procurement on a crash basis at some belated time. The lists should be available with the delivery of the design and not with the delivery of the hardware. At that point it could be too late.

A utility company which utilizes the services of an architectural engineer and of NSSS and turbine suppliers, should incorporate requirements similar to those discussed above into the contracts with the A/E and principal suppliers, who, in turn, should incorporate these requirements into contracts with sub-tier suppliers having design responsibility.

If spare and replacements parts or materials provisioning analysis is accomplished at some time after the release of the design other approaches must be taken to assure the systematic identification of each spare and replacement part or material. One such approach is to provide an indented drawing list and to work through each drawing on the indented list on a system-by-system basis.

A primary objective in the process of identifying spare and replacement parts and materials is to provide the identification of the part or material in terms of the ultimate supplier's part number and nomenclature. In the absence of the ultimate supplier's part number and nomenclature, the utility may be forced to continue to procure spare and replacement parts and materials through an intermediate supplier and this may result in delay or additional cost, especially when dealing with balance-of-plant items. In addition, the availability of the ultimate supplier's part number and nomenclature enables the recognition of parts or materials which are duplicated from one system to another. Being able to identify multiple usage items further enables the utility to economize. Fewer total multiple usage spares need be procured, but one large procurement can be made in lieu of two or more smaller ones. For example if System A requires a single spare for vital Part 1 and System B also requires a single spare for vital Part 1, as well as System C--it would be recognized that two spares, instead of three would suffice, and they be acquired through a single order and not three separate orders. Of course, the same applies to the identification and quantification of bulk materials which have multiple applications.

Statistical Best Estimate

Without getting into complex statistical applications which are unnecessary for quantifying spare and replacement parts or materials for a power plant, the most appropriate approach appears to be the most simple as well. For a given item the analyst must estimate the expected operating hours for the period in question. Also, the estimated failure rate, use rate or depletion rate must be estimated. By dividing the former figure by the latter figure, a best estimate of the quantity of items for the period is derived. Unfortunately, for power plants there is a lack of adequate failure rate data. Nevertheless, the analyst must make the best estimate using the practical experience of maintenance engineering personnel. This is better than trying to establish a best estimated quantity on the basis of speculation alone. The analyst should also recognize that this method of calculating a best estimated quantity or a most likely quantity is predicated upon the assumption that the failure rate of the item is random or constant throughout the life of the item. This may not be the case for items which are susceptible to higher infant mortality failure rates.

An important point to note is that the determination of failure rates may go hand-in-glove with the performance of other design quality analyses such as probabilistic cause-and-effects analysis, or probabilistic failure modes and effects analysis or quantified reliability analysis--any of which may be a requirement of the design process. Much of the data is common to these analytical techniques. This tends to substantiate the economic justification for the performance of spare and replacement parts analysis in conjunction with these other analyses during the design phase.

Adjustments to Statistical Best Estimate

The best estimate of the quantity of items required for the period in question must be adjusted based on the consideration of a number of other factors. Among these factors are: the consequence of not having the spare or replacement item when needed; the procurement lead time for the item; the cost of the item; the repairability of the item; the susceptibility of the item to future design change; and the shelf life time of the item. Following, in turn, is a brief discussion of each of these factors.

If the consequence of not having a spare or replacement part or material is high, there may be a desire to add to the statistically best estimated quantity of spare or replacement parts or materials. Conversely, if the consequence is low, an economy may be achieved by "fudging" on the best estimated quantity.

Similarly, if the procurement lead time for the part or material is long, especially if long lead time exists in conjunction with a high consequence of not having the part or material, there may be a desire to provide a quantity which is higher than the best estimated quantity.

If the cost of the item is high, but the item is neither of high consequence nor of long lead time, an economy may be achieved by again paring the best estimated quantity.

Some items will be spared at the component level rather than at the piece-part level. In other words, some spares will be components and not parts. As such, these spares, themselves, may be repairable by the replacement of their parts. When a component spare is, itself, repairable the quantity of component spares may be reduced with recognition of the component repair turnaround time.

Sometimes costs and schedule expedienicies outweigh the need to maintain a certain performance level in which case a design may incorporate lesser items than would have been the case otherwise. In such cases there may be a desire to retrofit these items within improved items at some later time. In such cases, the quantity of spares for the lesser item should be reduced in anticipation of the forthcoming improvement change.

Similarly, if an item's shelf life is shorter than the period for which the analysis is being made, the quantity of spare or replacement parts or materials should be adjusted downward in recognition of the short shelf life of the item.

The pluses and minuses for each of these factors should be algebraically summed to determine the net adjustment to the best estimate quantity. When this adjustment is positive, it may be referred to as "required safety stock".

Special Reserves

In the case of a power plant, a special reserve may be established to accommodate the checkout, preoperational test, hot functional test and start-up test phases during which time there may be expected to be more failures than would be the case at a later time. This special reserve for test should be identified separately because upon conclusion of the test phases, this reserve is no longer required and the re-procurement setpoints should be adjusted downward in recognition of this fact.

Also, a special reserve should be established for emergencies. If a spare or replacement part or material is an absolute necessity to the operation of the power plant, a single unit of this item may be established as an emergency spare which would not be allowed to be used in any routine test or maintenance activity. The emergency spare would be retained especially for use in any case in which it were required to preclude a plant outage. Failure to abide by this restriction would destroy the purpose of the emergency reserve.

Summary

The main steps of the analytical process are: (1) to establish a system by which to assure the complete identification of spare and replacement parts or materials; (2) to identify the ultimate source of each part or material in terms of the ultimate source's part number and nomenclature; (3) to estimate a most likely quantity of spare and replacement parts or materials to be required for the period in question; (4) to consider a number of factors, other than statistical factors, from which to estimate safety stock; (5) to establish special reserves for test; and, (6) to assure that all of this is accomplished in a timely and economical fashion, preferably during the design phase.

TREND ANALYSIS

"The Key to Objective Corrective Action"

Robert G. Burns, Chief Engineer, Quality Systems Division
Quality Assurance Department, Stone & Webster Engineering Corporation
Boston, Massachusetts

This paper will describe the evolution of a quality performance trend analysis system developed specifically for application to large construction projects. This system adapts the techniques developed to analyze quality trends in the repetitive high-volume manufacturing environment and applies them to large nuclear power projects. If properly developed, a trend analysis system can provide a welcome relief from the most common action taken in the nuclear industry today: the "fire fight" or "witch hunt". Our current preoccupation with rushing from crisis-to-crisis defeats effective corrective/preventive action which must be a carefully thought out management process.

Stone & Webster has developed an on-line system which measures quality performance by analysis of returned inspection data. As it now exists, the program is the composite result of the following four distinct phases which will be discussed further.

- o PHASE I - Quality Organization
- o PHASE II - Program Development
- o PHASE III - Data Analysis
- o PHASE IV - Corrective Action

Phase I of this program, the structuring of our Quality Assurance Department, took place over a three-year period and resulted in the organization shown in Figure (1). The features of this organization are: the establishment of a design control function within the Engineering Department designated as the Engineering Assurance Division and the creation of a Quality Assurance Department independent of the Construction Department. The Quality Assurance Department continued to evolve until Phase I was completed by a reorganization on March 19, 1973, which resulted in the establishment of a Quality Systems Division and a Department Services Group.

Quality Systems Division, which is responsible for developing a standardized program with related performance measurement systems, became the quality engineering branch of the Quality Assurance Department.

Phase II was immediately initiated concurrent with the establishment of the Quality Systems Division. We considered the adverse impact of operating in a non-standard mode and its relation to trend analysis. The need for each project to have a totally unique system was serving to divide and conquer our efforts to establish a sound trend analysis system. The effectiveness of performance measurement is, in my judgement, directly proportional to our ability to establish standard operations and to adjust these operations in response to feedback data. Similarly, in non-standard procedural systems, the error rate (conflicts, omissions and additions) increases in proportion to the degree of projectization. Development of a standardized procedural system, applicable to multiple projects, took approximately three years and is depicted graphically in Figure (2).

Key Phase II program features are as follows:

1. Procedures are standard and relate directly to engineering specifications.
2. Detailed attribute lists are generated to accompany each procedure.
3. A standard report format, the Inspection Report (IR), see Figure (3), is an integral portion of the system.
4. Inspection Planning is no longer an optional effort but rather an identified duty.

A key decision was made, in conjunction with Item 3 above, to count the "goods" as well as the "bads". This may sound quite simplistic in retrospect, but it is the key element in our quality performance measurement program. How often have you seen systems that only measure "bads" while ignoring the process averages? The NRC, ASME and others quite commonly, and with some justification, use this technique.

In order to provide even further definition, we segregate deficient conditions of a simple or minor nature from those of a more complex nature. This approach identifies all items found by an inspector to be deficient as an unsatisfactory (UNSAT) item or condition. If this UNSAT is resolved by the seller (manufacturer) or the site constructor, it ends there. However, if the item must be referred to project engineering for disposition, the UNSAT is closed and the item reappears on a Nonconformance and Disposition Report (N&D) as a nonconformance. This two loop system places quality corrective action at the lowest most responsive level; also, it allows the data base to identify the following conditions:

1. Avoidance of effective corrective action by sellers or constructors.
2. Dependence or costly referral of all matters to project engineering.
3. Failure of project engineering to produce clearcut engineering direction in specifications and drawings.

A graphical depiction of the two loop system may be seen in Figure (4).

Phase III, Data Analysis, utilizes our large scale in-house computer capability. Data is collected in two forms: first, as hard copy to be coded or keypunched for entry into an IBM 370/168; and secondly, by the most desirable direct entry from job sites.

Data, once entered, is stored, retrieved and manipulated to make use of the data base. We currently produce a number of status reports, measurement and test equipment reports and quality performance reports. The Keyword Statistics Report, shown in Figure (5), is one example of a quality performance report.

This report is issued on a project basis with the capability of assembling data into an across projects summary to determine overall process averages. This report compiles and displays quality data in the following order:

- o Commodity (Pumps, Rebar, etc.)
- o Inspection Activity (Shop, Field, Final, etc.)
- o Total Population
- o Number Inspected
- o Number Unsatisfactory
- o Apparent Percent Defective (APD)

The APD is determined by the ratio of the Number Unsat to the Number Inspected, times 100. We have adopted this term to avoid confusing it with the true percent defective (TPD), which may be determined by 100 percent inspection of the population to determine actual performance without resorting to statistical inference.

In addition to raw statistical material, we provide the user with a listing of the worst three attributes in that month and the previous two months rates for those attributes.

The ultimate purpose of this report is to take corrective action, based on our overall and individual project performance. By digesting the mass of data on a project (see Figure (6)) we can bring problems into focus for both supervisory and top level management action.

At this juncture, I would like to point out some pitfalls to be avoided based on our development experience.

- o Do not assume an overly optimistic schedule in a standardized program. Your salesmanship and marketing ability in this matter, both internally and externally, will be equally as important as technical competence.
 - o Forms that work in a manual mode probably would not work efficiently in the machine mode without expensive key punch or coding buffer. We optimized our form to suit machine operation, allowing direct data entry by a clerical person.
-

- 1978 ASQC TECHNICAL CONFERENCE TRANSACTIONS 589
- o Do not assume people will understand or easily relate to such systems. Plan to accompany all developments with vigorous indoctrination and training.
 - o Do not assume your lofty motives are well understood by others. Get a bulletin and person-to-person contact campaign going to avoid surprises to system users.

I do not think we can or should eliminate corrective action on "gut-feel"--that is always a management prerogative; but, we have provided an objective measurement tool that, hopefully, will allow more timely and effective objective corrective action.

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LCS 790:70:549

COMPANY ORGANIZATION FOR QUALITY ASSURANCE STONE & WEBSTER ENGINEERING CORPORATION

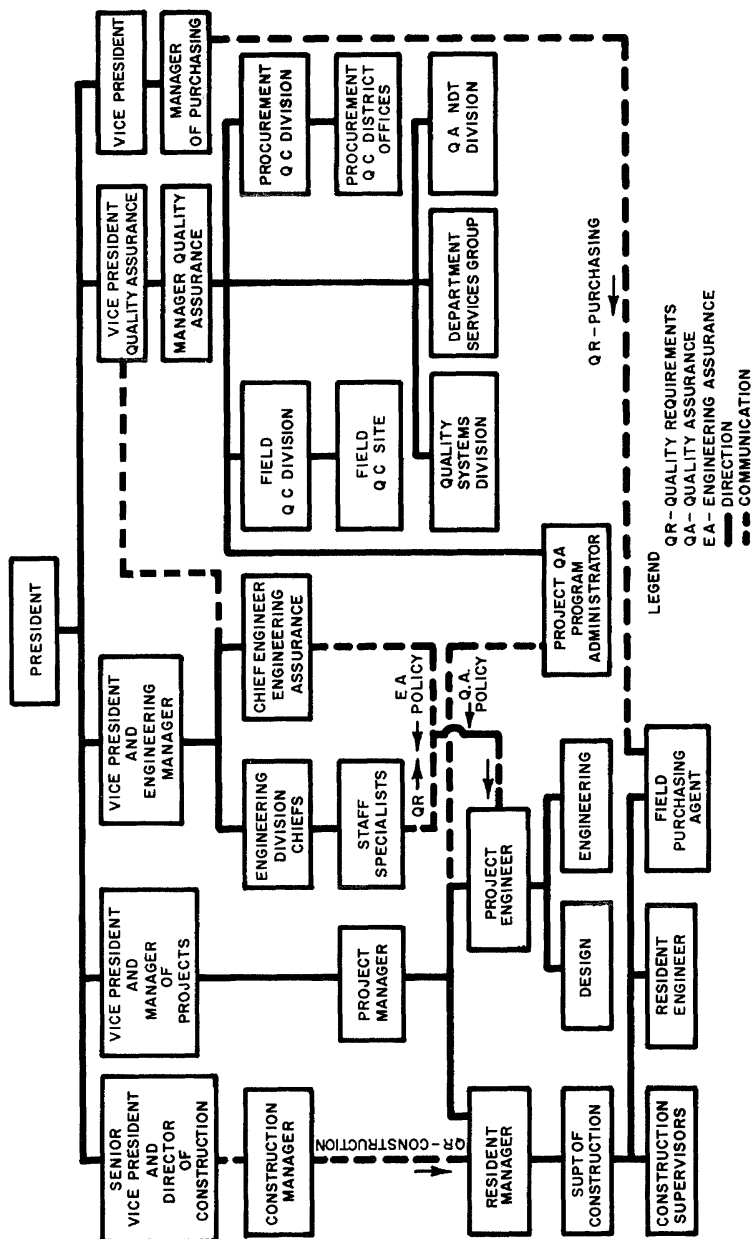


FIGURE 2

PROCEDURAL SYSTEM VS ORGANIZATION

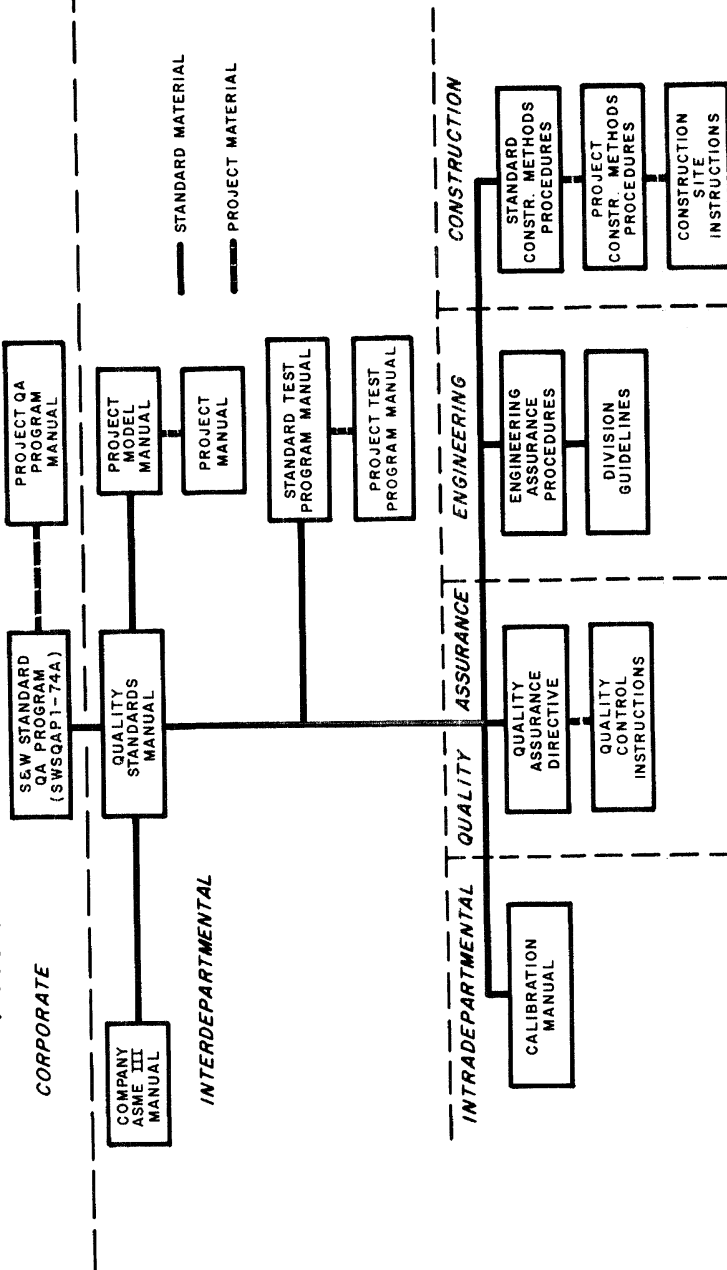
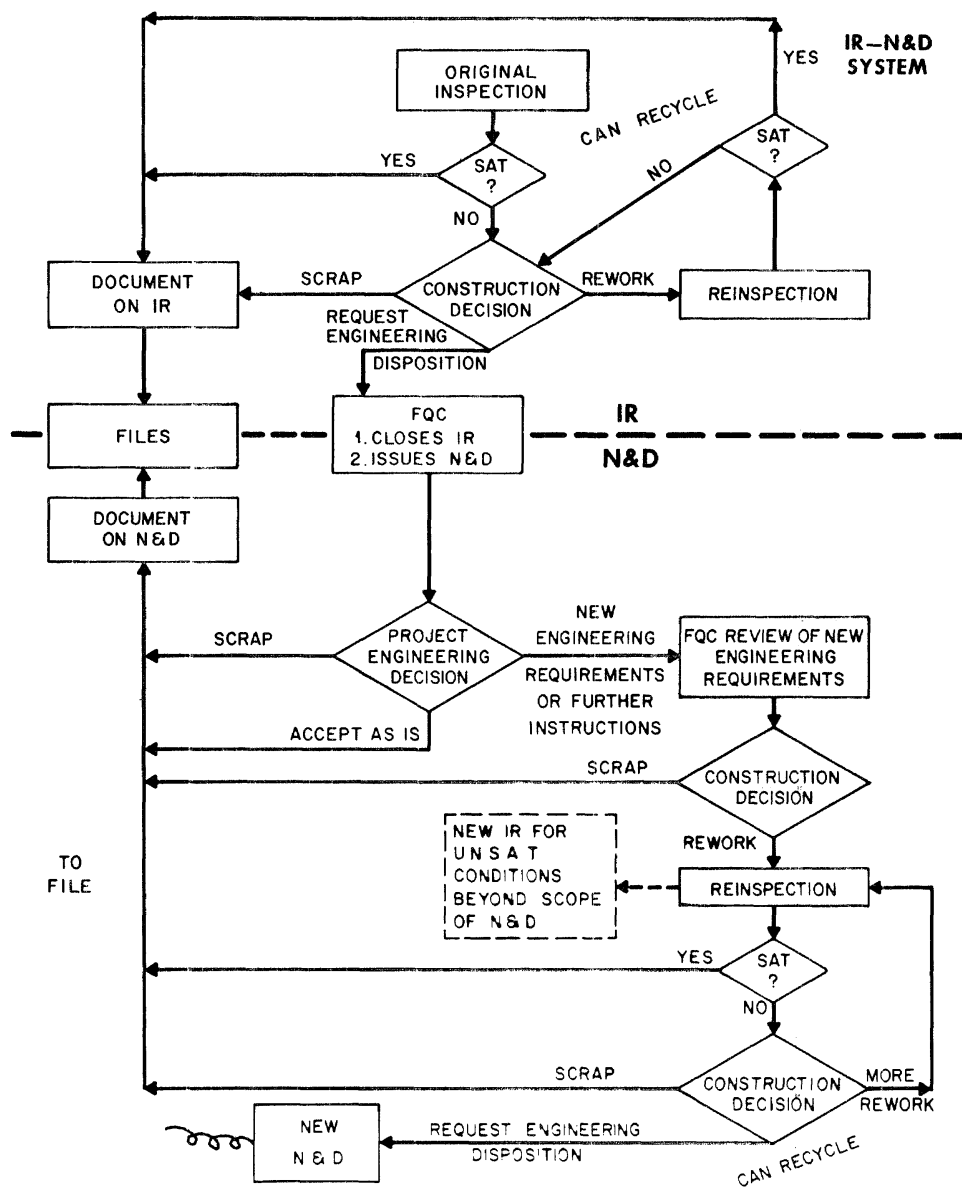


FIGURE 3

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ITEM DESCRIPTION																													
IR NUMBER										SHOP ONLY					KEYWORD					SYS CODE			FILE LOCATION CODE					QA CAT	
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FIGURE 4



STONE & WEBSTER ENGINEERING CORPORATION
QUALITY ASSURANCE DEPARTMENT

KEYWORD STATISTICS/ATTRIBUTE ANALYSIS REPORT

SAM JONES UNIT #2
110698.50

3/15/77
CONTRIBUTION BY PRINCIPAL UNSAT ATTRIBUTES
FEB77 JAN77 PREV 3 MO

PUMPS

SHOP INPROCESS		AVG UNSATS PER UNIT		PERCENT	
TOTAL POPULATION	UNITS	ATTRIBUTE		PERCENT	
NO. INSPECTED	UNITS	MFR RCRD-VENDOR FILED		32.9	
NO. UNSAT	UNITS	PROTECTIVE COVERS		16.4	
APP PCT DEFECTIVE		MACHINING		87.7	
		WELDING		8.7	
				6.4	
				3.2	
				8.6	

RECEIVING INSPECTION

TOTAL POPULATION		AVG UNSATS PER UNIT		PERCENT	
NO. INSPECTED	UNITS	ATTRIBUTE		PERCENT	
NO. UNSAT	UNITS	POC DOCUMENTATION		19.7	
APP PCT DEFECTIVE		IDENT/MARKING		8.4	
		PROTECTIVE COVERS		3.6	
				3.2	
				4.1	
				5.7	

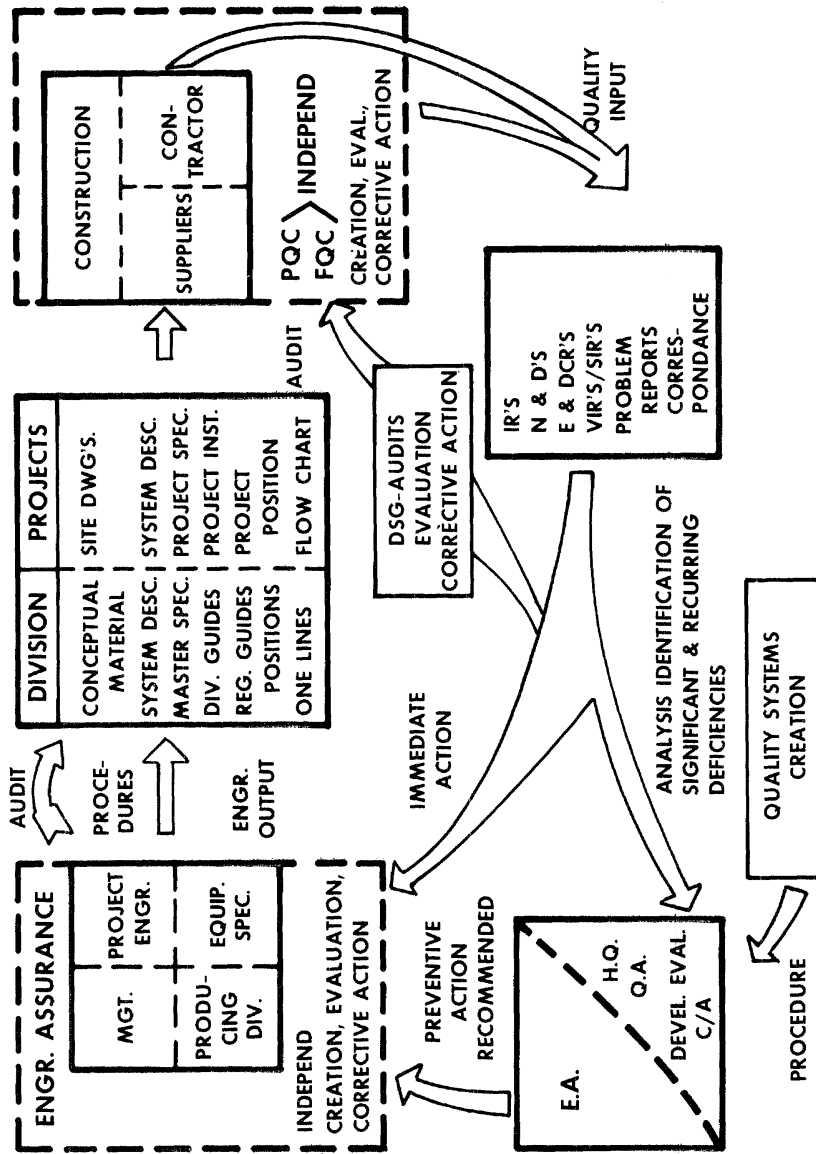
STRUCTURAL BACKFILL

INPROCESS INSPECTION		AVG UNSATS PER UNIT		PERCENT	
TOTAL POPULATION	CU. YDS	ATTRIBUTE		PERCENT	
NO. INSPECTED	INSPECTS	SURFACE PREPARATION		8.6	
NO. UNSAT	CU. YDS	INSTALL/PLACEMENT		3.1	
APP PCT DEFECTIVE		IN-PLACE DENSITY		1.4	
				2.3	
				4.8	
				3.8	
				7.2	
				9.1	

NOTE A: COMPUTATION OF "APPARENT PERCENT DEFECTIVE" IS NOT MEANINGFUL DUE TO SMALL POPULATION

NOTE B: COMPUTATION OF "APPARENT PERCENT DEFECTIVE" IS NOT VALID DUE TO INCONSISTENT UNITS

CORRECTIVE ACTION OVERVIEW



POWER GENERATION RELIABILITY
THROUGH THE BACK DOOR

Presented By
Jack E. Vessely
Manager, Quality Assurance
Florida Power & Light Company

It is true that money talks and therefore power plant availability will be having a loud voice in almost everyone's future. Availability, being one of the measurements of reliability, will in general become the focus of much attention as greater emphasis is placed on getting the most energy for the least cost. State and Federal legislation has been enacted and more being proposed, focusing on reliability. For instance, the Michigan Public Service Commission has established an incentive/penalty program to encourage Detroit Edison to improve its plant availability - offering the utility incentives above its allowed 13.5% return-on-equity if it can push system plant availability above the 85.1% level, or penalizing Detroit Edison if system plant availability falls below the 70% mark. The plant-availability-incentive provision was contained in DE's rate order dated May 27, 1977, and is believed to be the first time that such an incentive plan has been adopted in a major rate case by any state regulatory commission. Some of this legislation is enlightened and some is not, but whatever the cause or eventual effect, it is here and will continue to proliferate in the days to come.

One of the main reasons for improving availability comes down to a monetary concern. The major contributing factor is that power generation facilities cost so much to construct these days. To date much of our generation availability was achieved by having "X" percent of peak demand in surplus on standby. In 1967 the estimated investment cost for a nuclear plant was approximately \$135/KWe, with a 5 year service date. In 1973 the cost was \$520/KWe and up over \$1100/KWe by 1976, an increase of over 800% in nine years. With these types of construction costs you don't want to be building any more units than you absolutely need to have. Increases in individual plant availability have a large effect on when new plants are built or deferred.

The next major contributing factor related to availability is difference in operating costs between plants. Once a nuclear plant is built the cost differential of fuel involved in generating electricity, from oil or coal, runs at about \$20/MW hr. which comes out to \$350,000/day for a 700 MW nuclear unit.

The question I wish to address today is how we at Florida Power & Light are applying Quality Assurance techniques and other management systems to improve the reliability of existing nuclear plants. Suggestions, plans, recommendations and actions in this area abound. Many times those are based on the more visible aspects, the direct causes of forced outages. These are the items which get publicity and therefore become the subject of legislation. It is easy to read an article in the paper and then react by saying that the problem should not happen and then take action to see that it won't happen again. This works real well in the short range since the most obvious causes of failures usually effect availability. Things such as faulty valves and pumps in plants and transformers in distribution are common subjects of extensive reliability investigations.

A study was conducted for the Federal Energy Administration/Office of Energy Conversion by the Mechanics Research Inc. To identify and assess underlying causes of unreliability, our Turkey Point Plants were among the plants included in the study. Part of the study conclusion highlighted Turkey Point's ability to identify, resolve and implement corrective action.

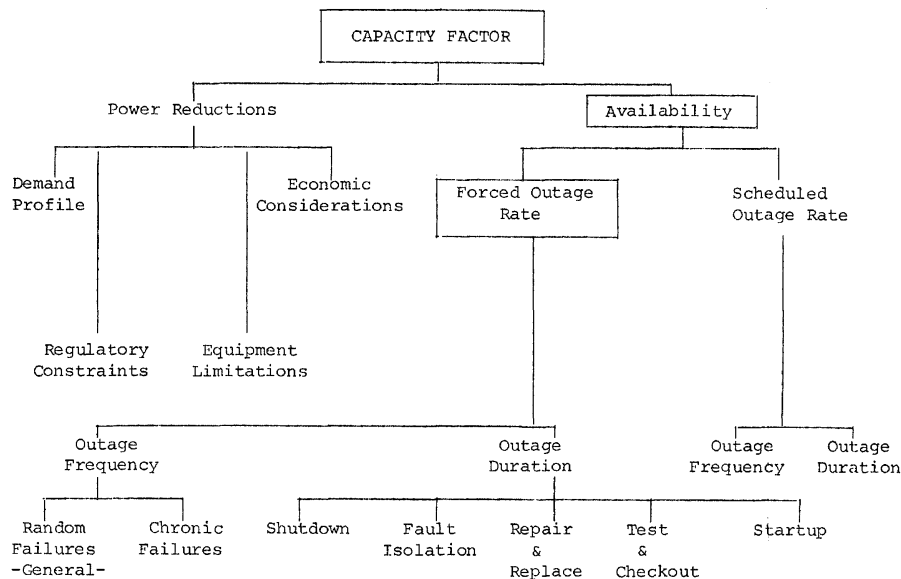
- Availability of special problem solving staff at the plant dedicated to the resolution of identified problems and recommend means of improving plant performances.

- Plant management authority and willingness to expedite.
- Training of plant personnel in trouble shooting.
- Economic trade-off analysis and management techniques to improve their problem solving capabilities.
- The higher level of instrumentation that provides useful pertinent data to help identify problems more efficiently.

At the present time most efforts are being applied in these areas. In achieving the 70 to 80% availability factors they seem to be meeting the needs, i.e., fighting the fires. However, in the future, to achieve 80 to 95% availability factors, we will need more sophisticated systems applications. The following examples show how short-range and long-range problems in availability are being addressed by Florida Power & Light.

At the present time none of the present FPL power generation plants have been purchased with specific reliability requirements, incentives for reliable design, or life cycle cost considerations identified in the procurement documents. Utilities purchased what the manufacturer had to offer on a turnkey basis, just like you buy a catalog item off the shelf. With that start in reliability the only thing you can do is to identify what you got, using performance to improve your reliability through failure history, thereby, the back door approach. And this is where Quality Assurance plays such a major role in the overall reliability system. This sounds like old stuff. You say this to utility operations or the engineering departments and they say that is exactly what we are doing, but are they doing it in a planned and organized manner or by fighting fires as they come up?

For the benefit of those who are not familiar with performance measurements of power generation plants, there is no single index which adequately reflects generating unit reliability. Three separate indices are used; capacity factor, availability factor, and forced outage rate. All three indices must be considered. An organized approach to reliability as a whole must address and assess equipment, personnel and environmental factors. A method must be in place for determining the effect of individual actions and reactions on other components and the entire plant. Figure 1 shows the typical relationship between reliability indices and primary influences.



TYPICAL RELATIONSHIPS BETWEEN RELIABILITY INDICES AND PRIMARY INFLUENCES

FIGURE 1.

At the present time we see many examples in the utility industry where reliability elements are being applied in various forms with various levels of sophistication to affect availability. Often these applications are made to correct specific existing problems without direct concern as to overall system reliability and do the job very effectively in that context. We at FPL are in the process of developing a power generation reliability system to be tailored to the existing structure so that the needs of the company be addressed. Also, problem areas are being investigated in both the quick fix, get the plant on line, and in a manner to improve the life cycle cost, forced outaged and availability factors of reliability.

The key or backbone to the back door approach to reliability is a good failure recording and reporting system. Four years ago the Power Resources Department of FPL developed a good failure recording and reporting system, a more long-range look at availability, called the Generation Equipment Management System (GEMS). This system addresses the problem of power plant outages, and is a good example of how a system is established to deal with a direct need through standardizing existing information into a usable form for big-picture application. The stated purpose of GEMS is to standardize the accumulating and reporting of power plant operation and equipment outages.

The system is established as follows. First let's look at input. Determination that a job needs to be done comes from three sources. The biggest source is the Plant Work Order, which can be generated by anyone who recognizes an equipment or area problem. A second source is planning meetings of supervisory personnel who decide what jobs should be performed. Finally, there is a preventive maintenance schedule which is reviewed monthly and additions, deletions or frequency changes may be made.

From each of these sources a Plant Work Order is generated which becomes the key to the reporting system. This form is filled out by anyone requesting work to be done and is reviewed by a foreman and supervisor. From there, a planner reviews the work, orders any necessary parts or equipment and schedules the operation. All work is then assigned on this basis on a daily schedule. The point of interest here is the fact that pertinent information from each Plant Work Order is coded for computer use in various applications. The following information is used. First there are code identifiers for plant, unit and the specific equipment involved. Next is the major code which identifies the condition which required that the unit or component be taken out of service or run at reduced capacity. Code sheets are regularly sent to plants to provide updated information as to potential problem causes. The manufacturer is then coded in or the fact that an outage was due to operator error. Very important to the overall system is the outage code which classifies an outage into forced, maintenance, overhaul, reserve, forced partial, scheduled partial, or preventive maintenance curtailing. Another important entry is the action code, which describes what is done to retain the unit to normal service. There is also a section for outage start date, outage end date, curtailed MW, manhours spent in repair, material cost, and contractor costs.

All this information is then available as output in various forms. First is the summary report. Besides the information on each unit described previously, there is effective outage information which accounts for the fact that several repairs can be performed in one outage. Also included is available hours, outage hours, operating availability, reliability, outage rate, forced outage rate and ratio, and scheduled outage rate. A section also covers various capacity factors for the system. Another report lists outage-related work that occurs within a time period, with occurrences grouped by related outages and is available for one or more plants. In addition to these standard reports there is a GEMS special report which can search the entire master file (all Plant Work Orders ever submitted) and extract specific information in a variety of fields including plant, unit, equipment, major cause of outage, manufacturer, outage cause, and other identifications, as well as within maximum/minimum manhour requirements.

The uses of this failure information to the overall availability picture are numerous. Among the present uses are determining principal causes of outage, reliability/availability statistics for future planning, unit reliability factors, operations and maintenance program improvements, new equipment purchasing guidelines, equipment maintenance history, provisions of operating information to comprehensive pools such as Edison Electric Institute.

Our next step in using the GEMS data is to determine the top 10 contributors to systems unreliability in each of the following design categories of plants:

- o Nuclear Plant - Westinghouse Design - 3 loop
Turkey Point Units 3 & 4
- o Nuclear Plant - Combustion Engineering Design - 2 loop
St. Lucie Unit 1
- o 400 MW Fossil - Ebasco Design
Turkey Point Units 1 & 2
Cape Canaveral Units 1 & 2
Port Everglades Units 3 & 4
Fort Meyers Unit 2
- o 400 MW Fossil - Mid-Valley Design
Sanford Units 3 & 4
- o 850 MW Fossil Plant
Manatee Unit 1

The intent is to focus the attention on the most active causes and work on them in a planned, organized, cost effective manner, rather than a forced outage situation.

As you can easily see, this system is capable of taking existing data, putting it into useful form and giving useful information as to how short-term decisions can affect long-run performance. In this context, availability is becoming a solid management tool for the industry.

Finally, reliability is being applied to programs involving systems applications. One problem facing utilities today is the decision whether to build new generating facilities or defer them and if a plant is to be built, what type unit and how large. This process becomes more complicated as growth patterns fluctuate more rapidly, as production costs increase and as diversification opens up new avenues with more opportunities and more choices to be made.

Historically, the calculation of production costs represented an area where much estimation had to be made. Planning studies were inaccurate because the input relied on approximations and the output was affected to that extent. One of the major variables involved in any estimation of this type is reliability through the forced outage rate. This variable is subject to a number of parameters including type of plant and length of time in service with new plants going through numerous minor problems and older plants having more unexpected breakdowns. For a variety of reasons these conventional methods consistently underestimate the utilization of high cost peaking units, and consequently underestimate the real cost of production.

Our approach to this problem is through PROCOS, designated a production cost program, which employs probabilistic techniques to obtain accurate predictions of unit loadings. This system basically tells what units should operate at what times to give most efficient operation. To do this a load shape is established for a given month. Then, a determination is made as to how to have units on line to meet that load shape. The basic variables involved here are plant maintenance schedules, heat rates, load points (minimum, middle and maximum for each plant) and forced outage rate.

Of interest here is the forced outage rate which is defined as the probability that a unit would have to be brought off the line for maintenance before the next weekend. That is, the maintenance could not be delayed beyond that time. This rate is an input into the PROCOS program and utilizes much of the existing availability data to arrive at solid estimates of forced outages. As presently operated the rate for each plant comes from three sources. Edison Electric Institute publishes data by unit class (such as 100 MW range) and type (oil, coal, etc.). Other utilities and industry information is also relied upon. The major input, however, is historical data. This comes from a variety of sources including maturity statistics for particular plants and the GEMS system. In this manner forced outage rates are established for each plant and this information is used to come up with a graphical representation known as a system loss-of-load-probability, (the likelihood that the system will not be able to meet the load demand) and is a primary factor in determining which plants should be operated to minimize operating costs of the system.

The PROCOS program can thus be seen as a means by which availability is applied on a system basis to greatly reduce generating costs. In this way we are helping meet the challenges of today through effective analysis and planning.

In summary, these are examples of how the management of one utility deals with the problem of generation system availability. A number of different approaches are currently being used including correction of existing day-to-day problems, tailoring of system approaches to the existing utility structure, and setting up long-range systems for planning purposes.

The situation still has a ways to go in the days ahead. Among the areas yet to be established are failure indices at the total system level based on availability at the point of use including generation, transmission, and distribution. The composite performance required can then be used to develop quantitative worth measurements reflecting actual economic values of the quality of electric service to the customer.

LCS 811:70:549

QUALITY SYSTEMS AUDIT

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I. The Quality Systems Audit is a management concept that can be utilized in a variety of ways, at different management levels. Since the purpose of this paper is to reflect principles and methodology of an audit based on my experiences, it will be presented based on my specific circumstances. Hopefully, it will be useful in a broad sense to you who may have similar or different needs in the audit area.

II. There have been many articles published on this, or similar subjects, with emphasis on what to audit and detailed checklists. Although I intend to expand the details to some degree, I will also try to highlight the practical complexities of an audit from an overall business standpoint, rather than just the philosophical Quality Control outlook. Additionally, I will attempt to highlight the how-to of any audit.

In my present capacity, I have the responsibility for performing Quality Systems Audits on international and domestic operations. The purpose of these audits is to help the local operations in pinpointing quality-related weaknesses and strengths within that operation and to provide Corporate management with an assessment of each operation's quality performance, thus leading to appropriate improvement programs. Now that the stage has been set, the following is a list of principles which may be considered as guides in performing audits:

- A. Forewarn of upcoming audits.
- B. Estimate the length of the audit.
- C. If the audit is in a non-English speaking country, arrange for interpretation, as necessary.
- D. Establish the objectives of the audit.
- E. Review the background of the operation to be audited.
- F. Once on-site, outline the schedule of events with local management.
- G. Record results during the audit.
- H. Summarize with Quality Control Manager.
- I. Summarize with local senior management.
- J. Issue a timely report, including strengths, weaknesses and auditor recommendations.
- K. Follow-up.

These principles, having been derived empirically, need to be expanded in order to understand the audit procedure:

A. Forewarning

As a target, try to notify local management of an upcoming audit at least two (2) months in advance. The scheduling of an audit should be a mutual agreement. Springing a surprise audit upon an operation will not buy you anything except resentment from that operation's management and future difficulties. Remember, you aren't trying to trap the Quality Control department, you are

trying to help them reach a common objective, be they an operation within your own company, or within some other organization. Furthermore, if you don't have a common objective with the operation, your auditing will most likely be fruitless.

B. Estimate Length of Audit

This is not only a matter of courtesy, but allows the local management to plan for availability of personnel. Keep in mind how you would like to be treated if the roles were reversed.

C. Translators

This is self-explanatory. I would caution, however, that if you do get involved with facilities where English is not the mother language, be certain that the translator is truly fluent in English and not simply the one in the plant with the best English, for that might be far from adequate.

D. Establish the Objectives of the Audit

This is a key element in conducting a successful Quality Systems Audit. It entails answering three questions:

1. Why am I doing the audit?
2. What am I going to audit?
3. What is the reference scale to be used in rating the Quality System?

1. Why am I doing the audit?

The first question has a variety of answers, depending upon the circumstances; be it an operation within your organization, a source of supply, etc. Regardless of the circumstances, however, the answer(s) should include provisions for: a) appropriate improvement programs based on whatever weaknesses are identified, b) identifying those responsible for implementing the programs and c) a system for monitoring progress. Without these ingredients, the audit will have little value.

2. What am I going to audit?

The second question contains the detail of audit, itself. I have chosen a list of key elements in the make-up of a Total Quality System (a term coined by A. V. Fiegenbaum) with important constituents highlighted within each element:

A TOTAL QUALITY SYSTEM

1) Management of Quality

Quality Control should participate as part of the management team. Principal functions include but are not limited to:

- a. Developing quality policies/procedures.
- b. Reviewing consumer use tests, purchaser studies, competitive and other field product tests.
- c. Improving product quality.

- d. Monitoring and reducing quality costs.
- e. Training and developing personnel.
- f. Analyzing consumer comments and taking corrective action, as applicable.
- g. Establishing attainable quality goals and objectives.
- h. Conducting quality self-evaluation, i.e., auditing own performance.
- i. Establishing and implementing product and process control plans.
- j. Organizational efficiency.

2) New/Changed Product, Process, and Package Control

Control of new/changed products should consider the designing, reviewing, and/or establishing of the following, as applicable:

- a. Calendar for planned new product introductions.
- b. Design review.
- c. Consumer use test.
- d. Specifications; performance, safety, and visual standards; classification of defects; and test methods.
- e. Test equipment.
- f. Product life and reliability studies.
- g. Written inspection plan for manufacture of the product.
- h. Test data showing conformance of initial product to specifications.

3) Purchased Materials

The quality system should provide for procurement of acceptable purchased materials and services by means of:

- a. Proper selection of vendors regarding quality.
- b. Issuance to vendors of appropriate specifications, test methods, gages, and mutually acceptable AQL's.
- c. Inspection, analysis, and control of purchased material per the written quality plan.
- d. Assessment and review of vendors' performance.
- e. Quality assistance to vendors, as needed.

4) Control during Manufacture

In-process control techniques should be established so that finished product meets specifications, while minimizing the overall cost of quality on the manufacturing floor, by providing for:

- a. Target values of key characteristics.
- b. Acceptance limits of variability about these target values.
- c. Methods of measurement.
- d. Inspection, analysis, and control of material during manufacture per the written quality plan.
- e. Information feedback for process correction.
- f. Disposition procedures for non-conforming product.

Products contract-filled or packaged should be produced in accordance with specifications and quality levels.

5) Control of Outgoing Quality

An inspection plan for finished product and packaging should be established so that product complies with applicable quality requirements by providing for:

- a. Characteristics to be controlled and the degree of compliance necessary.
- b. Type of inspection necessary (100% sorting, sampling, etc.)
- c. Inspection, analysis, and control of finished product and packaging per the written quality plan.
- d. Data collection and feedback for periodic review.

6) Special Studies

Special studies should be used to support all aspects of total quality control, with particular emphasis placed upon improving quality and reducing costs by means of such techniques as:

- a. Process capability studies.
- b. Defect prevention studies.
- c. Quality cost analysis and reduction.
- d. Specification review and modification.
- e. Gage and instrument qualification.

7) Gaging & Instrumentation Control

Control of all gages and instruments should be exercised so that data generated is reliable and truly measures the product or process to which it applies. This system should cover all gages and instruments--both in-line and off-line--with respect to:

- a. Design.
 - b. Set-up and operation.
 - c. Updating maintenance and repair.
-

8) Documentation Control

All quality systems should be documented and should provide for timely issuing and updating of:

- a. Specifications.
- b. Sampling plans, inspection instructions, and test methods.
- c. Gage/instrument drawings and their associated instructions.

The documentation procedure should be fully integrated with the procedures used by other functions.

9) Quality Information Feedback

A Quality information feedback system should be set up to provide means for data collection, analysis and reporting on all phases of quality and to form the basis for taking appropriate corrective action. The type of quality information includes, but is not restricted to, the following:

- a. Quality levels--purchased materials, during manufacture, and finished product.
- b. Quality Costs.
- c. Consumer comments.
- d. Competitive quality levels.

10) Materials Identification and Control

A system for materials identification and control should be established for:

- a. Identifying and controlling materials from incoming through finished goods inventory regarding their quality status.
- b. Allowing for required traceability.

11) Consumer Comments

A system should be set up, in order to be cognizant of and responsive to consumer comments, by providing for:

- a. An orderly and systematic record, evaluation, and control.
- b. Affirmative and effective corrective action.
- c. Prompt and full response to consumer inquiries and service.

12) Personnel Training and Development

This approach should consider:

- a. Appropriate orientation or training for those people directly assigned to quality responsibility and orientation to those whose job impinges on quality.
- b. Training of back-up personnel.

13) Quality Self-Evaluation

Each Operation or Subsidiary should evaluate the effectiveness of its own quality effort.

- a. Evaluation of outgoing product quality, independent of routine inspection.
- b. Evaluation of all quality activities--those directly assigned to the quality organization as well as others--should cover:
 - (1) Product and process.
 - (2) Gaging and instrumentation.
 - (3) Stores and distribution systems for raw materials and finished goods.
- c. Quality self-evaluation should be carried out according to a planned schedule with the participation and/or support of the Factory Manager, the Quality Manager, and the managers of other factory line functions.

It is these elements plus the interaction of the Quality Control group and other functions such as Marketing, R&D, Purchasing, Distribution, Production, Industrial Engineering, etc. that are to be audited.

3. What is the Reference Scale?

The third question is the most complex. Those aspects of quality in terms of such indices as outgoing product quality levels, may be easily assessed if there are established numerical targets and limits. The difficulty comes when you try to score such things as: a) management ability, b) extent of follow-through within each element, c) contribution to the total manufacturing effort, d) effectiveness of training, e) appropriateness of the goals being set, etc. The approach you may consider, and one I've found successful, is similar to that of Quality Costs, as depicted in Dr. Juran's Handbook. The Quality Cost tool is used primarily to pinpoint areas which offer maximum opportunity for improvement. We are sensitive to the risks associated with comparing Quality Costs to indices such as sales, number of people, production levels, etc. These can be too arbitrary and may lead you down the wrong path.

Much the same approach can be applied to auditing results, i.e., use the auditing information to pinpoint those areas which need improvement while maintaining the strengths within the organization, avoiding the use of arbitrary scales! Therefore, my answer to the question "What is the reference scale to be used in rating the Quality System?" is to let the list of weaknesses, recommended improvements, and identified strengths speak for themselves.

E. Review Background of The Facility

Every operation may not have the same needs in their quality control activities, nor the same emphasis on the various elements, as other operations. Each operation should tailor its quality control efforts to fit their business needs and so the auditor should have an understanding of the other business aspects to help ensure those needs are understood. The auditor should review such aspects as:

- Financial Status
- Product Lines
- Process Types
- Other Quality Indices
- Past Audits, if any
- Local Applicable Laws
- Local Labor Conditions
- Market Atmosphere, i.e., Economy, Competition, etc.

F. On-Site Schedule

It is advisable to initially meet with the Quality Manager in order to explain the sequence of events in the audit, including the people and places you plan to visit. This allows sufficient time for personnel to adjust their schedules. This itinerary may and should also include functions within the operation, such as Material Control, Purchasing, Marketing, etc. It is also advisable to leave some unplanned time in case you have to modify the schedule or back-track, depending upon your findings.

G. Recording Results

As you conduct the audit, i.e., reviewing inspection and calibration data, reviewing documentation, asking questions, requesting demonstrations, following the flow of material, etc. there is a need to record the findings. This can be done in many obvious ways: by memory, a note pad, portable tape recorder, taking copies of documents, samples of product and/or photographs. You may think of others. My own preference is using a note pad and requesting copies of documents. I would be especially apprehensive of using a tape recorder as it has a tendency to inhibit people. At this time, two items are worthy of comment:

- It is my opinion that the best auditor is no match for an operation that wants to stymie an auditor; therefore, to be successful, you must try to instill a feeling of mutual respect and confidence.
- One item usually associated with Quality Audits is a checklist. I must admit my bias against them for they tend to require so much attention of the auditor that the opportunity to observe and interpret is hindered.

To help better understand the detailed activity of an audit, the following is an example of how you might delve into one small aspect of a quality system. For simplicity, I have chosen element #9, Quality Information Feedback, section a. Quality levels.... A typical approach might be to: 1) review incoming, in-process, and finished product inspection data, 2) ask how, and if, this data is summarized and forwarded to the Quality Control office, 3) ask the Quality Control Manager to show you the file of data and how, and if, the data is reported to other appropriate operation functions, 4) review the distribution and contents of the report summary, 5) ask yourself: Are the right people on distribution? Is the summary clear? Is the frequency of reporting appropriate? Is there evidence of responses from the other functions?, 6) contact the recipients of the reports. Do they understand the reports? Do they think they need the reports? Is there evidence that they take action based on the reports? How do they see their responsibility to quality?, 7) review these questions, and answers, with the Quality Control Manager and see if there is a mutual understanding

between Quality and the report recipients. You and the Quality Control Manager should jointly assess the effectiveness of the feedback loop and the resultant action. If, however, the Quality Control Manager doesn't grasp the concept of this element, the recommended improvement program would entail upgrading management skills as well as instituting an effective system of information feedback.

This is, of course, a simple example but it does highlight the need to determine if: 1) an adequate feedback system exists, 2) Quality Control and the recipients of the data have common objectives and understandings, 3) the system triggers the intended useful action.

H. Summarize With Quality Control Manager

Upon completing the audit, review your findings with the Quality Control Manager, with two objectives in mind:

- 1) To ensure that your facts are correct. You may disagree on the conclusions; however, there must be no disagreement on the facts, otherwise the integrity of your report will be under suspicion.
- 2) To give the Quality Control Manager an opportunity to reflect on the results so as not to be confronted by his boss without the facts.

The success of future audits in that same facility will depend on how you conduct yourself in the first one.

I. Summarize With Senior Management Within The Operation

This is done for similar reasons as immediately above; but may be in different terms, depending upon the background of this level of management.

J. Report

Issue a written comprehensive report covering no more than what was discussed prior to the end of the audit; but including outstanding strengths within the organization, areas requiring improvement, and recommendations for those improvements.

K. Follow-Up

Assuming that the auditor will maintain contact with an operation after the audit, the operation should issue a program for corrective action and subsequent progress reports. The auditor should use the original audit and appropriate progress reports as a basis for a future follow-up audit to measure the overall improvement. This phase is the true test of the effectiveness of an auditing activity.

QUALITY ASSURANCE INFORMATION SYSTEM AT KCL

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To quote Dr.Juran, ' Quality Assurance is an activity of providing to all concerned the evidence needed to establish confidence that the quality functions are being adequately performed '.

The confidence is established through an objective evidence and this evidence is derived from the documentary records. In other words, the document becomes an essential base of Quality Assurance. Mere documents alone do not sufficiently establish the confidence that quality functions are being performed, but the information derived from the analysis of such documents will finally become a controlling factor to serve the purpose of assurance to the consumer.

At Kirloskar Cummins we have tried to base our Quality Assurance information system on this philosophy. Before I give information on the Quality Assurance information system at Kirloskar Cummins, let me explain briefly what is Kirloskar Cummins.

The Kirloskar Cummins complex is situated at Pune, 100 miles south of Bombay in India, employing approx.1750 personnel and engaged in the manufacture of Cummins diesel engines of various models ranging from 60 to 800 h.p.

Kirloskars are pioneers in the manufacture of Diesel Engines in India, and have been practising advanced quality control techniques in their organisations for quite a long period of time. The quality control movement in the engineering industry of our country owes its success to a very large extent to Kirloskars' foresight in adopting these techniques, successfully.

The Quality Assurance information system provides three tier analytical reports every month. The basic purpose is to educate and involve personnel at all levels right from the operator to the top management in various quality activities at the plant. Consideration is also given to provide information which could be easily digested.

We have processed the information available through Quality Systems, on EDP. When the first few Quality reports were released to Line Managers, one look at the heaps of computer printouts were a tough proposition for them to digest. It added to their confusion and all reports were neatly placed by them on the racks without any corrective action. It was realised that there is a communication gap and which required to be filled up. Further it was found out that sorting of information into 'vital few' and 'trivial many' was essential to fill-up the communication gap. This has to be done with prior knowledge of product and process and with understanding of what could be 'vital few' and which required correction. This was done manually. Manual analysis of data as a system was possible only because of its homogenous nature and comparatively smaller volume of production.

Initially the need for and the type of documentation required at various stages of quality control activities have been established.

A reorganisation in the working set up of our Quality Control Division was required to ensure authentic and first hand information.

The reorganised functions of Quality Control are explained briefly in Figure 1.

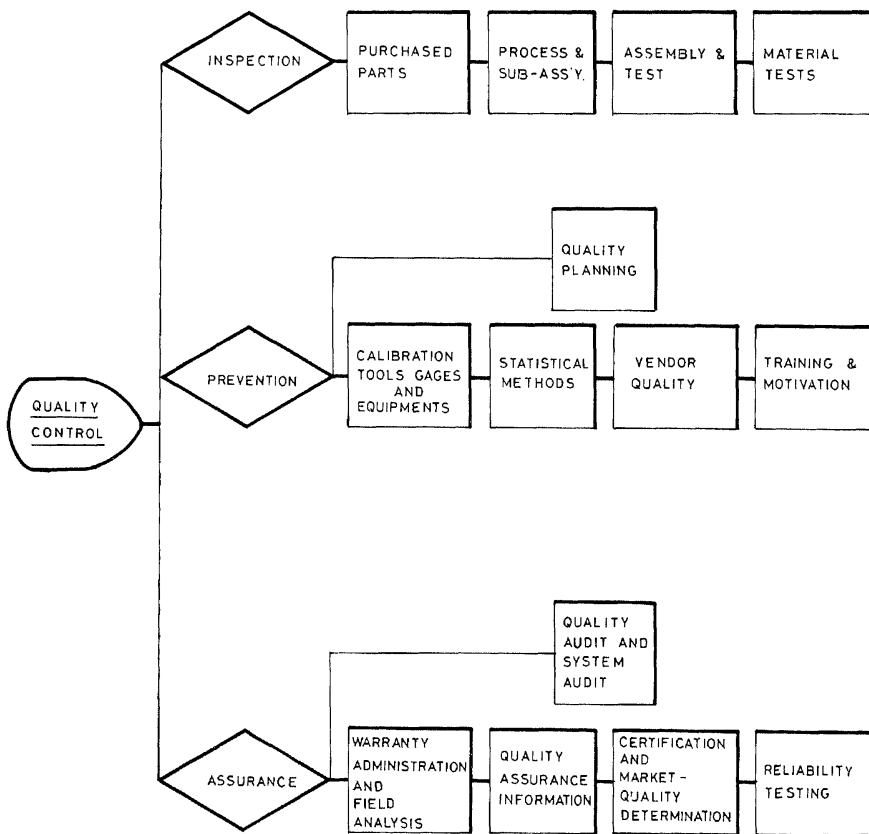


Figure 1

There are some new responsibilities added to Quality Control which as a convention were not with them. This was done to widen the horizons of Quality approach. For example, Warranty administration and customer Liason which is a new addition. Certification of product by external certification agencies like Lloyds Register/American Bureau or Factory Mutual/Under Writers Lab etc. was an additional responsibility. These new horizons were required for Quality personnel to enlarge their out look of Quality problems and get first hand knowledge of customers point of view about the product. This has also helped in effectively forming a Quality Assurance information system and implementing corrective action.

The new working set up facilitated compilation of data from documents and an analysis of first hand information proved useful in initiating corrective action.

A primary report which is for the information at the operator level is a simple bar chart which is released every month to be exhibited on various production lines. This bar chart indicates the cost of controllable manufacturing scrap. It is impressed on the operator that had he avoided occurrence of the scrap, the Company would have gained the money. Figure 2 is a specimen of this reporting method.

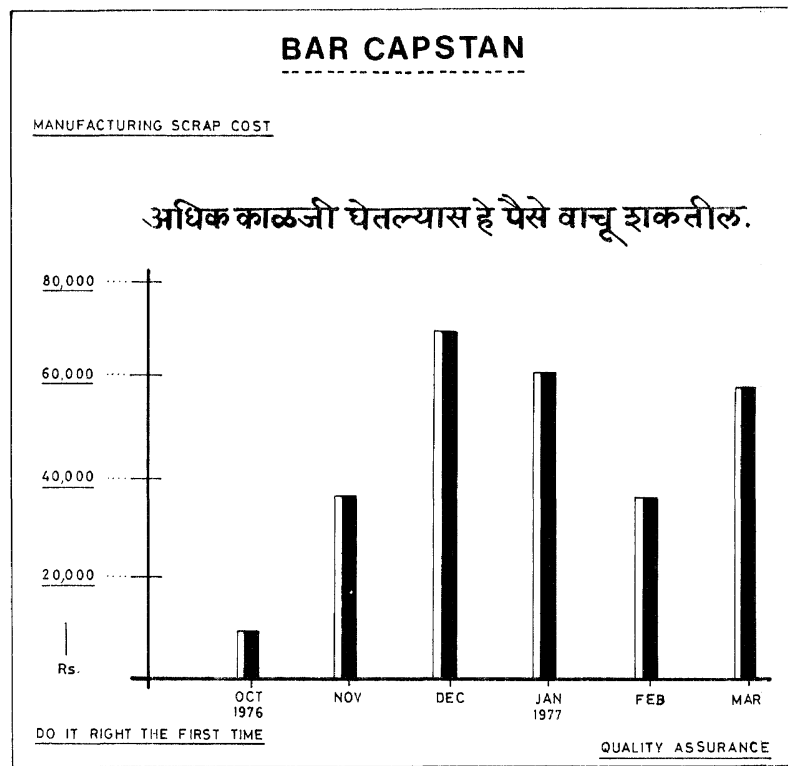


Figure 2

This method of reporting has a direct impact on operators and lead to competition between Sections to keep the controllable scrap cost low.

The second report of the three tier reporting system is for the use of the Line Manager or Foreman level. This is a middle management level and the corrective action implementation is always at this level. This report gives all the vital information of quality deficiencies in components manufactured in their section. The Line Manager gets information on the rejection quantities of his section during a period, the reasons for rejection, the cost of rejection etc. He is further informed of the component performance, on the assembly and testing stage, which is machined and processed in his section. Through this report he also knows the field performance of the components manufactured in his section. Discrepancies observed during the product quality audit are also given to him for the corrective action implementation.

In short a periodic quality information is available to him right from the manufacturing stage to the field performance. Figure 3 represents a specimen of this report.

TO : LINE MANAGER, Camshaft Section CC: MANAGER QUALITY CONTROL
 FROM : QUALITY ASSURANCE MANAGER, MANUFACTURING
 SUBJECT : REJECTION STATISTICS FOR December 1976 MANAGER, DEVELOPMENT
 MANAGER, PROCESS ENGINEERING
 CHIEF INSPECTOR, PROCESS
 CHIEF INSPECTOR, PPI

Audit Inspection

Camshaft bearing dia. found o/s by 0.0002" for half width of the bearing in audit inspection of the engine.

Monthly summary :

TOTAL QTY. INSPECTED	QTY. MFG. SCRAP	COST MFG. SCRAP Rs.	QTY. VENDOR SCRAP	COST VENDOR SCRAP Rs.	QTY. SAL/ RW	ASSY. REJ.	FIELD FAILURES
386	62	38745	14	10864	51	2	1

Details:

PART NAME & NUMBER	TOTAL QTY. INSP.	MFG. SCRAP QTY.	VENDOR SCRAP QTY.	COST	SAL. REJ. QTY.	ASSY. REJ.	FIELD FAIL.	REASONS
Camshaft, 143450	181	19	-	12882	-	-	-	Cracked H.T. fault (3) S.F.m/c fault (9) Grinding fault (3) Material fault (4)
129870	184	20	-	7496	-	-	-	Turning steps on brg. dia. (1) Gear mtg. dia.u/s(6) Brg. concentricity out (3)
	-	-	-	1124	-	-	-	Brg. dia.u/s (1) Cracked - H.T.fault (6) S.F.M/c fault (9) Grinding fault (4)
	-	-	3	-	-	-	-	Forging pocket (3)
	-	-	-	-	-	-	-	Pocket to cam base (2) Cam u/s to remove forging pocket (10) Liner dimn. u/s (5)
	-	-	-	-	-	2	-	Oil hole shifted (15).
	-	-	-	-	-	-	-	Cambush seized.
	-	-	-	-	-	-	1	Broken near collar. Improper radius.

CONTD.....2

CONTD2

Figure 3

Line Managers and shop inspection supervisors hold meetings regularly to study the report and corrective actions are planned.

Higher Management is reported with an overall view of the Quality activities in the plant and product performance in the field.

The third tier information to higher management contains Quality Indices, quality trends, outgoing quality levels, as derived from audit results, quality costs of internal and external failures, significant quality problems which require higher management attention and corrective actions implemented as a result of weekly meetings.

Separate reports are prepared every month for the procurement department which is provided with information on vendor performance. Vendor performance reports include the cost of rejection of supplies and vendor quality rating during that period and quality trends in the supplies.

Apart from these, analytical reports on product reliability tests, quality systems audit and product field performance are released periodically. The idea is to provide accurate and exhaustive information to concerned departments for effective corrective action and avoid field surprises.

Figure 4 indicates the source of information and the quality assurance information system at Kirloskar Cummins.

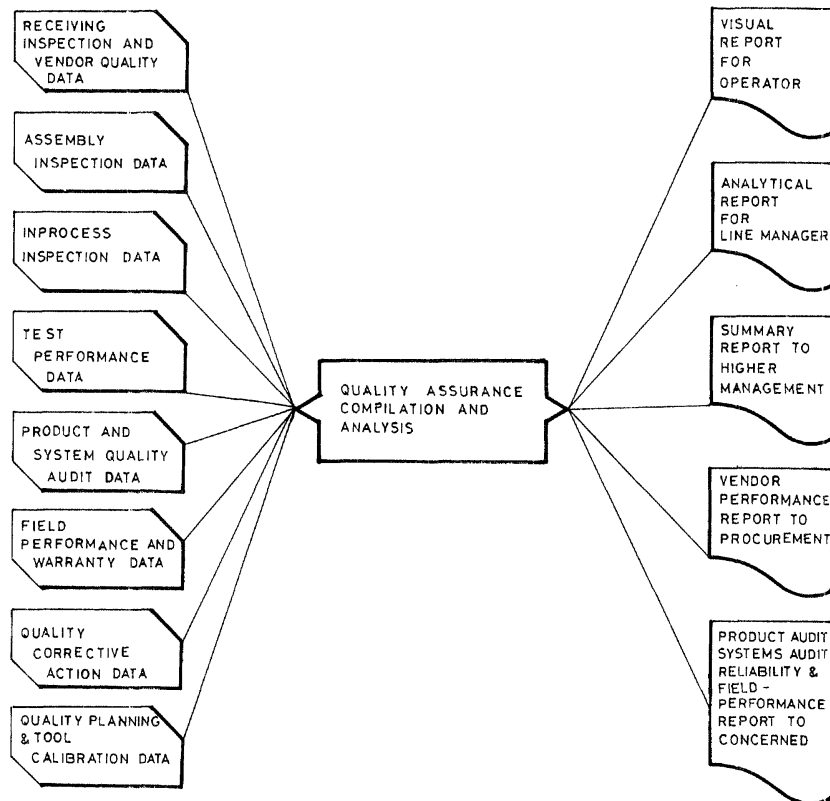


Figure 4

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MINI-MIZING CALIBRATION PROBLEMS

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OVERVIEW

One view of a calibration system is to see it as an expense to be kept as low as possible. A second view sees it as a technician who shows up periodically to tinker with the measuring devices only to disappear minutes before the device stops working completely. Unfortunately both views are often brought about by the failure of the calibration department to adopt a systems approach to its position in the overall Quality Information System.

The following material describes a simple but effective mini-computer based calibration system which focuses on the following goals:

- Providing top management with information on the dollar value of its instrumentation investment and the overall "health" of those instruments.
- Providing operating departments with essential information on individual instruments.
- Providing calibration personnel with an up to date data base for a) maintaining control, and b) effecting change towards improved levels of performance.

THE SYSTEMS APPROACH

A popular joke has an aircraft pilot announcing to his passengers as bad news that they are totally lost and running low on fuel and as good news that they are making excellent time. It is all too tempting to approach calibration control in the same manner. The enormous increase in both the quantity and complexity of instrumentation in the past decade has left many calibration departments barely able to keep up with day to day demands. In such an atmosphere it is not surprising to find that implementation of even modest systems improvements can result in significant dollar savings.

As shown in figure 1, proper control requires a) knowledge of what is required, b) knowledge of current performance, and c) the means for doing what is required.

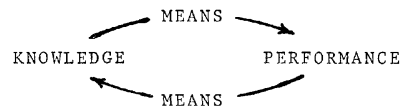


Figure 1. Basic Control Loop

TOP MANAGEMENT FOCUS

In performing its function of optimizing profitability, top management operates best when it has facts on which to base its decisions. A successful calibration system recognizes and responds to this need. The data base in the MINI-CAL System contains the actual replacement cost for each instrument. When totaled, this figure often gives top management a clearer picture of the size of the instrumentation task than any other figure. Quantity, however, is also reflected by figures which show both the total number of instruments and the total number of measurement channels. The importance of the latter figure becomes clear when one realizes that some measuring instruments contain over 80 separate measurement channels (each requiring calibration).

Thus by providing meaningful figures on cost and quantity, the system is able to relate to top managements desire for a dollarized, quantified measure of the task being undertaken.

CUSTOMER FOCUS

A user of instruments is much more likely to remember the one time an instrument failed than the hundreds of times it didn't. Realizing that this is basic to human nature, the MINI-CAL System was developed to present meaningful reliability and performance figures for each department serviced. Measures of accuracy and precision (to be discussed later) as well as the number of both scheduled and non-scheduled service calls are kept for each instrument. These figures are incorporated into monthly reports which are reviewed with the user departments thus engendering a close and mutually supportive relationship between the calibration group and the departments being serviced.

INTERNAL FOCUS

The third area focused upon by the MINI-CAL System is that of the calibration department itself. Recognizing that clear cut lines of responsibility are essential for task management, each instrument is assigned to a specific engineer-technician team within the department. With this information as part of the data base, each team receives routine reports showing the status of those instruments for which they are responsible. Monthly reports are generated by the computer showing instruments due for service so that an efficient servicing schedule can be planned. In addition, a monthly exception report is generated showing instruments not calibrated on schedule as well as instruments having substandard reliability, accuracy, or precision. By highlighting those instruments with performance problems, the system provides a feedback loop for engineering corrective action as well as tightened calibration schedules.

The calibration manager, thus prepared with cost and quantity figures for top management, with performance figures for departments serviced, and operating results for substandard instruments is able to maximize overall calibration effectiveness.

SYSTEM HARDWARE

A Hewlett-Packard model 9830-A Mini Computer with an INFOTEK Corp. 16K Memory Expansion Supplement forms the hardware base for the system. In addition, a Hewlett Packard model 9867B Mass Memory and a model 9869A card reader are used for data storage and input respectively. Hardware costs were between \$30K and \$40K. (Note: While it has not been tried, the author is confident that most if not all of the features of MINI-CAL could be achieved using floppy disc technology for a total cost of under \$20K.)

Time required to input all data and run all reports is approximately 4 hours per week, thus the prorated hardware cost for the entire system is \$500/yr. as shown below:

40,000 Purchase Price
+10,000 10 Yr Maintenance & Overhead
\$50,000
x 0.10 Assuming 10 Yr Life
5,000/Yr
x 0.10 Fraction of 40 Hrs/Wk
\$500/Yr = Annual Hardware Cost for MINI-CAL

DATA BASE

The MINI-CAL data base consists of the following information elements stored on the mass-memory disc for each separate instrument.

- | | |
|-----------------------------|---------------------------------|
| 1) Calibration ID# | 14) Procedure Availability |
| 2) Description | 15) Location - Bldg./Floor |
| 3) Asset # | 16) Dept. No. Used By |
| 4) Serial # | 17) User (Title or Initials) |
| 5) Drawing # | 18) Last File Update (Date) |
| 6) Type (Mech, Elec, Etc.) | 19) Last 3 Repair Symptoms |
| 7) Number of Meas. Channels | 20) Last 3 Repair Causes |
| 8) Replacement Cost | 21) Last 3 Accuracy Reports |
| 9) Dept. Purchased By | 22) Last 3 Precision Reports |
| 10) Date Installed | 23) Last 12 Mos* - Sched. Calls |
| 11) Cal Due Frequency | 24) Last 12 Mos* - Sched. Hrs. |
| 12) Responsible Engineer | 25) Last 12 Mos* - Emer. Calls |
| 13) Responsible Technician | 26) Last 12 Mos* - Emer. Hrs. |

* By Month

While most of these data elements are self-explanatory, two of these deserve additional comment.

Accuracy = Difference between Lab Standard and Local Reference Standard (Worst Channel)

Precision = Range of 5 repeat readings on same part (Worst Channel)

Due to memory size and programming considerations, it was decided to input to the computer only the worst channel results. In addition, both figures were converted to a per cent figure by dividing by the appropriate product tolerance. Thus:

$$\text{Accuracy (\%)} = \frac{.001" \text{ error}}{.020" \text{ total tolerance}} = 5\%$$

With this feature as part of the data input all system users from top management to servicing technicians are able to judge the accuracy and precision "health" of the instruments. This in turn permits factual discussion concerning company goals for measurement error. Expressing accuracy and precision as a % of product tolerance also leads simple rules for establishing when an instrument is no longer fit for use, and must be repaired.

Note: Programming and practical factors limited storage of accuracy and precision to six digits. This resulted in rounding all errors of 100% or greater to 99%. Storage was thus limited to the last three checks.

Example - Accuracy @ 159905 means:

15% error at beginning of latest service
>99% error at beginning of second latest service
5% error at beginning of third latest service

EQUIPMENT SERVICE RECORD - DEPT. 535											
CAL. #	BUILDING	FL.	DEPT.	AC	PR	SY	RE	HRS.	MO.	DAY	FR.
E	0	0	0	0	0	0	0	0	0	0	0
C	1	1	1	1	1	1	1	1	1	1	1
P	2	2	2	2	2	2	2	2	2	2	2
L	3	3	3	3	3	3	3	3	3	3	3
I	4	4	4	4	4	4	4	4	4	4	4
A	5	5	5	5	5	5	5	5	5	5	5
M	6	6	6	6	6	6	6	6	6	6	6
I	7	7	7	7	7	7	7	7	7	7	7
I	8	8	8	8	8	8	8	8	8	8	8
I	9	9	9	9	9	9	9	9	9	9	9

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FIGURE 2. INPUT CARD (FRONT)

[illegible]

FIGURE 3. INPUT CARD (BACK)

DATA INPUT

After determining what data was needed by the computer, the question of HOW remained. How to input the data to the system so as to:

- a) Minimize Input Errors
- b) Minimize Input Effort

In looking at the options of keyboard vs. card input, the advantage of card input became readily apparent when one considered the approximately 100:1 speed advantage of cards. Not having a keypunch convenient to the department determined that mark-sense cards would be used, although a strong desire for single document handling would have probably lead to the same decision.

The card front (Figure 2) contains blocks for the following data:

Col. 1 = Type of service call. E = Emergency;
C = Calibration; P = Preventive Maintenance;
L = Instrument Lost; I = Instrument Inactive;
A = Instrument reActivated; M = Instrument Moved
Col. 3-6 = Calibration Number
Col. 7 = Optical subset designation within a cal. number.
Col. 9-15 = Building/Floor Location of Instrument
Col. 17-19 = Department number using Instrument
Col. 21-22 = % Accuracy (worst case, before adjustment)
Col. 23-24 = % Precision (worst case, before adjustment)
Col. 26-27 = Symptom Code (if any)
Col. 28-29 = Repair Code (if any)
Col. 31-33 = Hours to complete service
Col. 35-37 = Date service completed
Col. 40 = Number of separate service calls covered by this card.

The card back (Figure 3) is used for data recordings, as well as a source document for initial data on a new instrument. The columns PAR 1, 2 ... etc. serve for recording calibration data by paragraph # when referencing formal calibration procedures. The installation portion contains in addition to the obvious entries, the following coding for principles of operation:

M = Mechanical	P = Pneumatic
E = Electrical	D = Densitometric
O = Optical	S = Sensitometric

SYSTEM SOFTWARE

The MINI-CAL software has been constructed to allow ease of data base manipulation and report generation. Programs written in BASIC provide the following functions:

PUTIT: Interactive keyboard input of new instrument information from back of mark-sense card.

MCARD: Batch feed of mark-sense cards through card reader to update data base.

FIXIT: Interactive keyboard program allowing updating of any data base element.

EXREP: Prints out monthly exception report for each building showing each instrument which:

- a) was not calibrated within the allocated frequency where W = Weekly, M = Monthly, A = Annual, etc.
- b) exceeded prescribed accuracy or precision limits.
- c) had more than 4 emergency service calls.

EXCEPTION REPORT - BUILDING R1				DEC 1977	PG 1		
TECH	CAL#	DESCRIPTION	ACCURACY	PRECISION	EMER CALLS	LAST CAL	FR
14	49	SPEED OF PULL	153020	*	0	771116	M
19	1451	RADIOMETER	*	010624	0	*	W
- SUMMARY -							
-----COMPLETED-----				MISSED	AC/PR	-EMERGENCY CALLS-	
	INST	CHECKS	HOURS	IN/CK	>20%	0	1 2 3 4+
EMERGENCY	5	5	6.4	--	--	152	5 0 0 0
SCHEDULED	75	130	88.0	3/3	3	--	-- -- -- --
TOTAL INST SERVICED = 77				TOTAL INST = 252			
* = Within specified limits this month							

Figure 4. EXREP Report

FULREP: Prints out monthly report by building showing calibration status of all instruments at that location.

ALL INSTRUMENTS---BUILDING R1				MONTH OF DEC 1977					
TEC	CAL#	DESCRIP	ACC	PREC	SCHED #	HRS	EMER #	HRS	LAST CAL
14	85	AIR GAGE	101010	201515	1	0.3	0	0.0	771207
19	155	CAP GAGE	100515	152005	0	0	1	0.5	771031
TOTALS					135	94	11	10	

Figure 5. FULREP Report

ALPHA: Prints out an alphabetic listing of all instruments in the system.

CAL#	DESCRIP	DWG#	LOC	DEPT	USER	COST	ENG	TEC	PCD	FR
85	AIR GAGE	A283521	R1-2	346	SUP	3.0K	2	21	N	M
552	XRAY CAP	D391030	R1-2	412	SUP	1.1K	7	14	Y	A
TOTAL INSTRUMENTS = 1127										
TOTAL MEASUREMENT CHANNELS = 2072										
TOTAL INSTRUMENT COST = \$2,421,200										

Figure 6. ALPHA Report

CALCHK: Prints out activity report covering last 12 months.

#26	POD	TESTER	FREQ=M	LAST CAL = 771201	LAST EMER = 771130								
		JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
SCHED FR	1	1	1	1	1	1	1	1	1	1	1	1	1
SCHED HR	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.6	0.4	0.4	0.5	0.4	0.4
EMER FR	0	0	0	1	0	0	1	0	0	0	0	0	0
EMER HR	0.0	0.0	0.0	1.0	0.0	0.0	1.5	0.0	0.0	0	0.0	0.0	0.0

Figure 7. CALCHK Reports

TECHS: Prints out report of all instruments assigned to a given technician. Instruments due are designated by *; those missed the previous month are designated by **. Each technician is given a printout at the first and third weeks of every month.

--K. ANDERSEN's INSTRUMENT LISTING 1/01/78									
CAL#	DESCRIPTION	ASSET#	BLD-FL	DEPT	LAST CAL	FR	ENG	PCD	DUE
26	POD TESTER	4146	R1-2	385	771201	M	7	Y	*
85	FORD ROLLER	3721	R1-1	372	771115	M	7	N	**

Figure 8. TECHS Report

NUMREP: Numerical listing of all instruments in the system (similar in format to ALPHA).

DEPREP: Lists all instruments purchased by and/or used by a given department (similar in format to FULREP).

CONCLUSION

This paper has described one company's success in implementing a mini-computer based calibration system. While return on investment figures for prevention activities are difficult to substantiate those managers who are familiar with MINI-CAL agree that it has been one of our most successful systems engineering ventures. And finally those who rely on the data from the instruments serviced by MINI-CAL sleep just a little bit better each night.

CONSUMER PROTECTION ORIENTED SAMPLING PLANS

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ROGERS, ARKANSAS

INTRODUCTION

The only quality level acceptable for defects which cause injuries is zero. It has long been recognized that in most industries this is not attainable. The producer has the responsibility for maintaining the quality of his product, and through knowledge of his product and of the relationship of the defect to the injury, he can pick the most realistic sampling plan to give the consumer the level of protection he needs.

This document establishes sampling tables designed such that the emphasis is on the prevention of defects from reaching the consumer. Contrary to the traditional Quality Assurance approach in the design of sampling plans, economics has been sacrificed in favor of accuracy. For ease of application, only single sampling plans are used. It may be used in conjunction with 100% inspection, or under proper circumstances, as an alternative. These plans are to be used as part of a Quality Assurance program. Total reliance on them does not guarantee that no defective product will reach the consumer.

Recognizing that the most published sampling plans are oriented around the top end of the OC curve in order to minimize the producer's risk, it is obvious that the consumer's risk is allowed to vary a great deal. In the application of sampling plans involving defects that could cause injuries, the control needs to be oriented around the lower end of the curve. Because a number of variables are involved, several levels of protection are required. The most important variables to consider when choosing a sampling plan are: 1) The probability of injury given the defect exists; and 2) The severity of the injury.

Because the most popular and most widely accepted current publication of sampling plans is the MIL-STD-105D, the layout and format of the MIL-STD-105D is used in this document. Terminology and procedure were copied from MIL-STD-105D whenever possible.

EXPRESSION OF LEVEL OF QUALITY

AOQ and AOQL - AVERAGE OUTGOING QUALITY and AVERAGE OUTGOING QUALITY LIMIT.

The AOQ is the average quality of outgoing product including all accepted lots or batches plus all rejected lots or batches after the rejected lots or batches have been effectively 100% repaired or inspected and all defectives replaced by nondefectives. The AOQL is the maximum of the AOQ's for all possible incoming qualities for a given acceptance sampling plan. To estimate the total defects reaching the consumer during any given time period, multiply the AOQ times the total product shipped. If the AOQ is not known, use the AOQL.

TQL - TOLERANCE QUALITY LEVEL.

The TQL is the maximum permissible fraction defective of any single lot.

P(A) - PROBABILITY OF ACCEPTANCE.

A lot having a process average (Fraction Defective) equal to the TQL selected will have a probability of P(A) of 0.05 of being accepted. This indicates that 95% of lots that are this percent defective will be rejected.

SELECTION OF SAMPLE

UNITS OF PRODUCT

The unit of product is the item inspected for the purpose of determining its classification as defective or nondefective or to count the number of defects. It may be a single article, a pair, a set, a component, or an end product.

LOT OR BATCH

The term lot or batch shall mean a collection of units of product from which the sample is to be drawn and inspected to determine conformance with the acceptability criteria and may differ from a collection of units designated as a lot or batch for other purposes.

FORMATION OF LOTS OR BATCHES

The product shall be assembled into IDENTIFIABLE lots, sub-lots, batches, or in a manner prescribed by usual Quality Control practices. Each lot or batch shall, as far as practicable, consist of units of product of a single type, grade, class, size and composition manufactured under essentially the same conditions and at essentially the same time, and must be capable of being isolated.

LOT OR BATCH SIZE

The lot or batch size is the number of units of product in a lot or batch.

SAMPLE SIZE

The sample size is the number of units of product selected to be inspected. For any given lot size, the corresponding sample size may not be smaller than indicated in Table I.

REPRESENTATIVE SAMPLING

Samples must be representative. They may be random or stratified or a combination of both.

ACCEPTANCE AND REJECTION

ACCEPTABILITY OF LOTS OR BATCHES

Acceptability of a lot or batch will be determined by the use of a sampling plan or plans associated with the designated AOQL and TQL.

RESUBMITTED LOTS OR BATCHES

Lots or batches found unacceptable shall be resubmitted for reinspection only after all units have been screened and all defective units removed and/or repaired. All screened lots must be resubmitted. Screened and reworked lots should be subjected to the same sampling plan as new lots.

INSTRUCTIONS

1. Determine the AOQL.

If the minimum acceptable number of defects allowed to reach the consumer during any given period of time can be determined, divide this number by the total production for that period of time.

2. Turn to Table I. -- Using lot size and AOQL, determine the Sample Code Letter and TQL.

In the body of the table, the information is in the form of a letter, a decimal point, then numbers.

Example: For a lot size of between 2,001 and 7,000, when an AOQL of 0.0001 (1 in 10,000) is desired, the sample code letter and TQL are R.001. The letter is the Sample Code Letter, and the number is the TQL.

TABLE I - SAMPLE SIZE CODES

LOT SIZE	AOQL							
	0.0001	0.00025	0.0005	0.001	0.0025	0.005	0.01	0.025
0 - 80						D.04	E.05	
81 - 130					H.02	F.03		
131 - 300				K.01		J.02	H.04	
301 - 500			M.005		L.01	K.02	K.03	
501 - 1,000		P.0025		N.005			J.04	
1,001 - 2,000			Q.0025		N.01	L.02	L.03	K.05
2,001 - 7,000	R.001		R.0025		P.01	N.02	N.03	
7,001 - 15,000		S.001		T.0025		Q.01		
15,001 - 35,000		T.001		W.0025				
Over 35,000			W.001					

3. Turn to Table II. -- Using the Sample Code Letter and TQL, determine the sample size and Acceptance and Rejection numbers.

Example: R.001

Read down the extreme left hand column (headed Code Letter) until the letter R is found. In the next column to the right, the sample size of 3070 is found. Next read down the column headed (TQL =) 0.001 until it crosses the row containing R and 3070. This intersection (0,1) contains the Acceptance and Rejection numbers. More simply, R.001 indicates a sample of 3070 is to be inspected, and the lot accepted if no defective units are found or rejected if one or more defective units are found.

AOQL's are displayed on the right side of the table. A different combination of Code Letter and TQL may be selected SO LONG AS THE SAMPLE SIZE IS NOT REDUCED.

TABLE II - CHART OF TOLERANCE QUALITY AND AVERAGE OUTGOING QUALITY

SINGLE SAMPLE P(A) = 0.05																			
Code Letter	Sample Size	TOLERANCE QUALITY LEVEL								AVERAGE OUTGOING QUALITY LIMIT									
		.001	.0025	.005	.01	.02	.03	.04	.05	.001	.0025	.005	.01	.02	.03	.04	.05		
C	60	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
D	75	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
E	95	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
F	100	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
G	119	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
H	154	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
J	235	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
K	305	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
L	470	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
M	600	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
N	930	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
P	1200	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Q	1860	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
R	3070	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
S	4800	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
T	7730	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
W	10500	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
X	20500	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Curve Shown On Page																			



USE FIRST SAMPLING PLAN BELOW ARROW



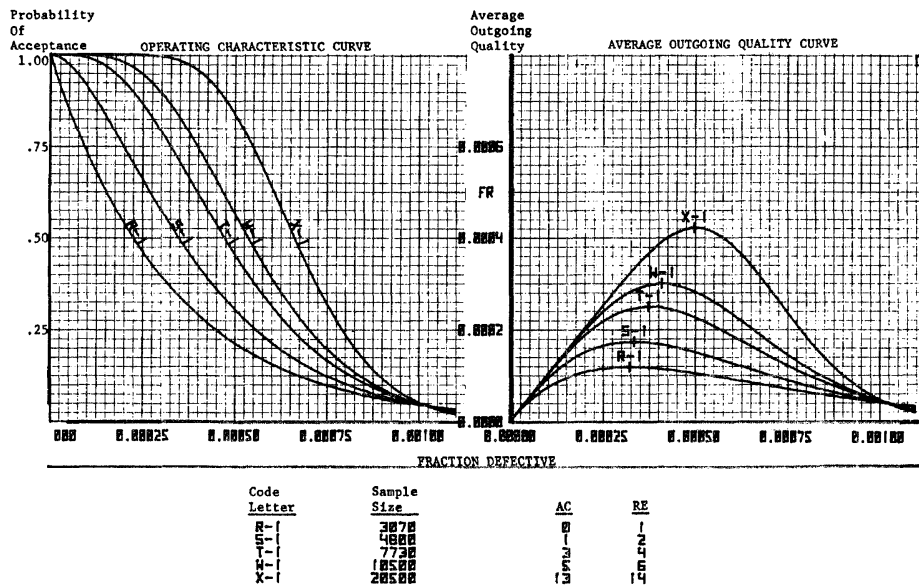
USE FIRST SAMPLING PLAN ABOVE ARROW

AC ACCEPTANCE NUMBERRE REJECTION NUMBER

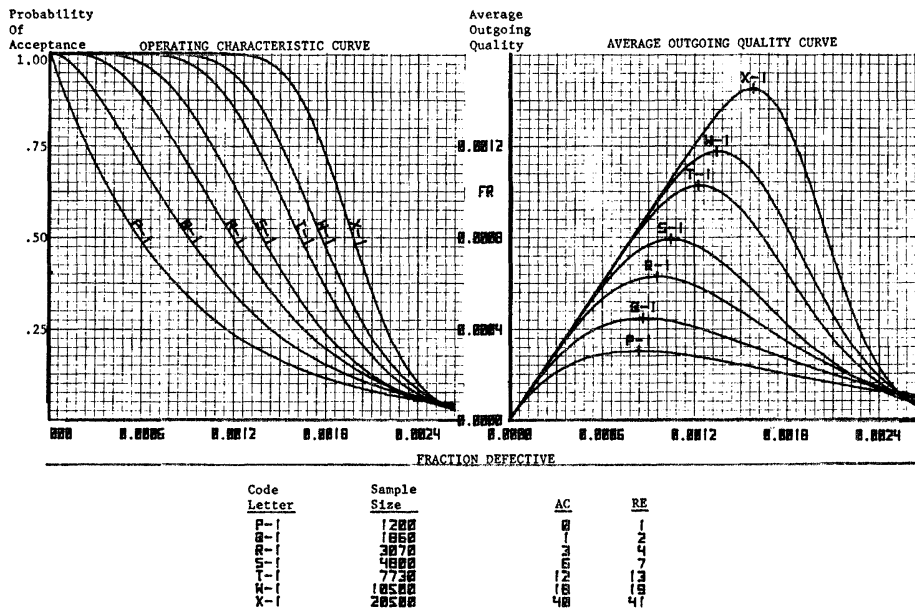
WHEN THE SAMPLE SIZE EXCEEDS THE LOT SIZE, 100% INSPECTION IS REQUIRED

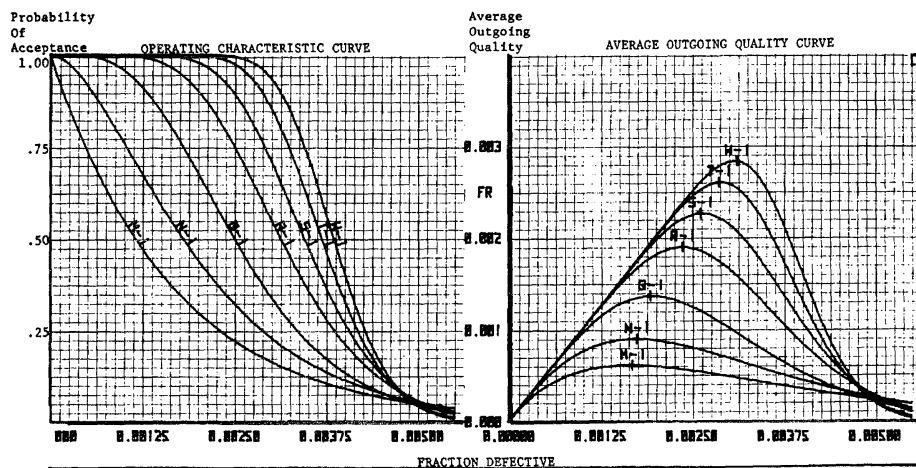
SWITCHING PROCEDURES

The charts on the following pages are OC curves and AOQ curves that represent all of the families shown in Table II, grouped by TQL. When the producer has used the prescribed sampling plan for a sufficient period of time to be confident in his estimate of the process average, he may refer to the charts and choose a smaller sample size having a comparable consumer's risk and a producer's risk that he feels he can live with. Switching should be accomplished only after a sufficient number of lots (at least ten) have been accepted consecutively using the current plan. Any time a lot is rejected, the original plan should be resumed and the entire procedure started over. The decisions surrounding switching, like the decisions regarding the choice of AOQL and TQL, are the responsibility of the producer and are based on his knowledge of the product and the process.



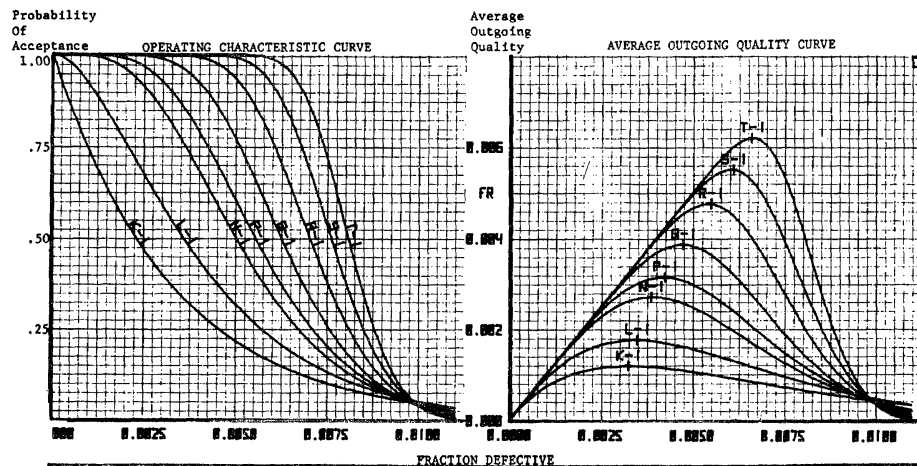
TQL = 0.0025





Code Letter	Sample Size	AC	RE
M-1	500	0	1
N-1	938	1	2
Q-1	1860	4	5
R-1	3870	9	10
S-1	4800	16	17
T-1	7730	28	29
W-1	12500	40	41

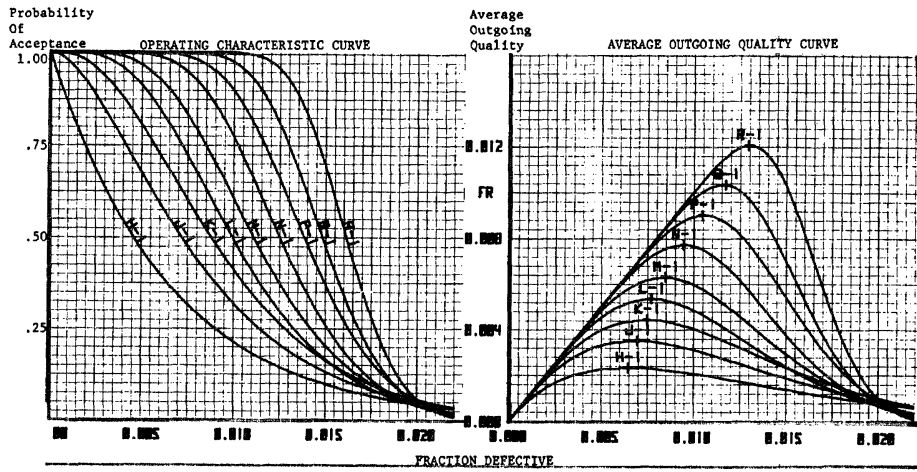
TQL = .01



Code Letter	Sample Size	AC	RE
K-1	305	0	1
L-1	470	1	2
M-1	938	4	5
N-1	1200	6	7
Q-1	1860	11	12
R-1	3870	21	22
S-1	4800	36	37
T-1	7730	62	63

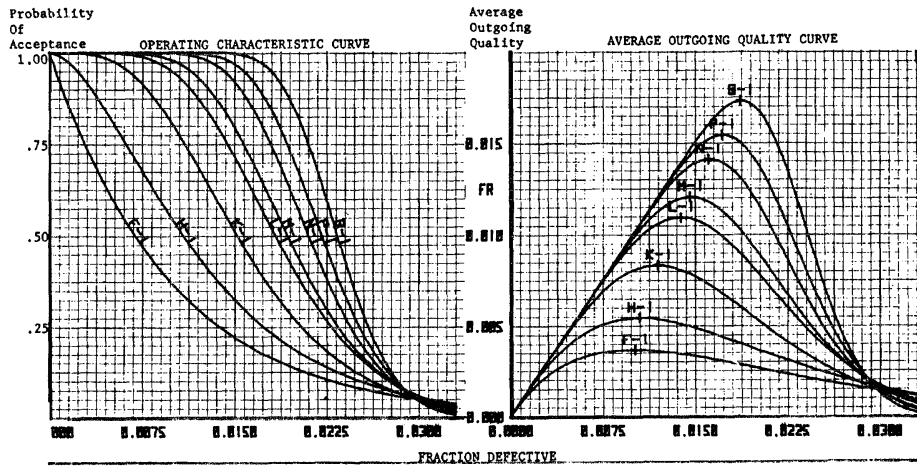
OC & AOQ CURVES

TQL = 0.02



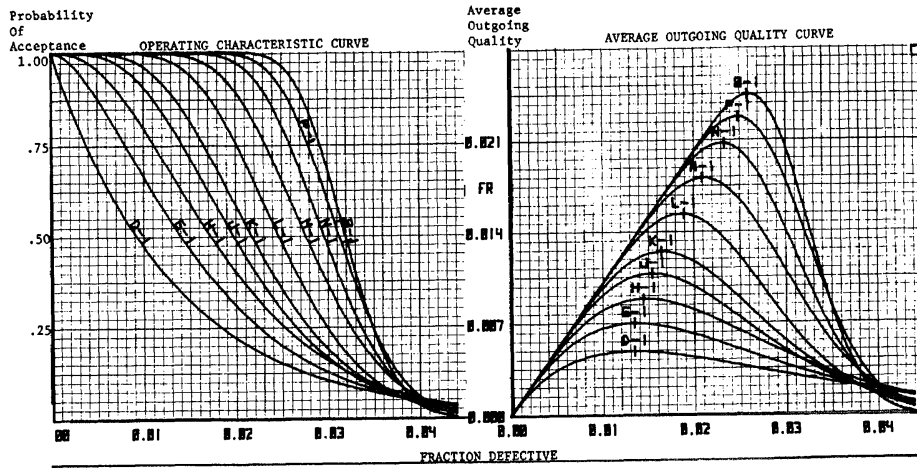
Code Letter	Sample Size	AC	RE
H	154	0	1
J	235	1	2
K	305	2	3
L	470	4	4
M	600	6	5
N	930	11	12
P	1200	16	17
R	1800	27	29
S	3070	49	50

TQL 0.03



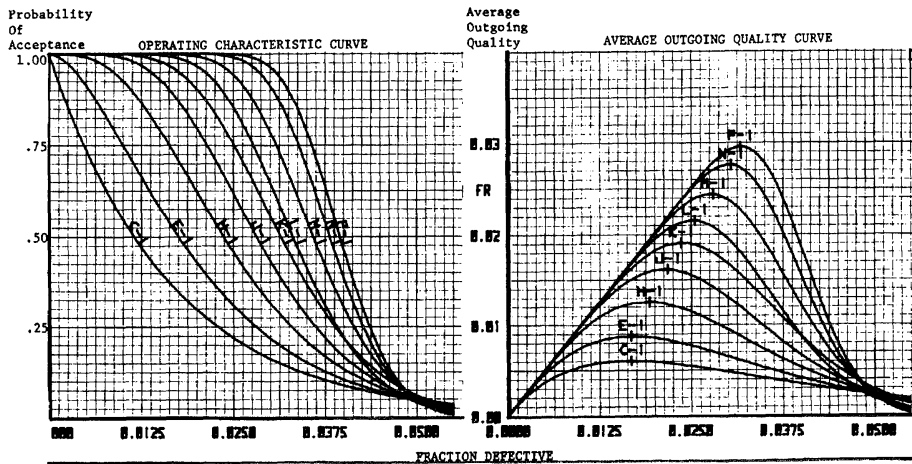
Code Letter	Sample Size	AC	RE
F	100	0	1
H	154	1	2
J	235	4	3
K	305	6	4
L	470	11	5
M	600	19	12
N	930	26	20
P	1200	43	27
R	1800	44	44

OC & AOQ CURVES
TQL = 0.04



Code Letter	Sample Size	AC	RE
D-I	75	0	1
G-I	119	1	2
H-I	154	2	3
J-I	235	4	5
K-I	385	6	7
L-I	478	11	12
M-I	600	16	17
N-I	938	27	28
P-I	1288	37	38
S-I	1668	59	60

TQL = 0.05



Code Letter	Sample Size	AC	RE
C-I	60	0	1
F-I	95	1	2
H-I	154	4	5
J-I	235	7	8
K-I	385	16	17
L-I	478	16	17
M-I	600	21	22
N-I	938	35	36
P-I	1288	47	48

CONSENSUS STANDARDS: A PROFESSIONAL VIEWPOINT

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The clinical laboratory industry is only one segment of the most rapidly growing industry in the United States - the health care industry! Expenditures for health in 1976 were 8.6% of the Gross National Product (GNP). Whereas the GNP increased 18% during the last two years, expenditures for health increased 31%. Public funds accounted for 40% of this expenditure and increased 15.6% in 1976. This is changing the focus of the limelight interest of government and Congress from ways and means to protect the public health welfare to their economic welfare to control this growing public fund cost for health. This is essential if the National Health Plan objective is to be accomplished as a political promise of the current administration by 1980.

The clinical laboratory accounts for only 7% of the health expenditure in contrast to 40% for hospital care, which is increasing more rapidly than the 20% for physician care. As an ancillary service to both, the clinical laboratory industry is a likely candidate for control. Witness to this the impact of the 1966 Medicare Act, Clinical Laboratory Improvement Act of 1967 and the Medical Device Act of 1976 on the clinical laboratory industry. All of these laws and subsequent regulations have involved and will further involve the process of standardization for the field. Many of the available voluntary standards (criteria or specifications) were adopted by government and made regulatory standards. Some were associated with other government written criteria to become the value standards required by Medicare and CLIA-67.

The individual pathologist, as the physician in charge of the medical laboratory, and organized pathology have long been involved in the establishment of "standards". These have evolved into a six phase management program of total quality control for the medical laboratory:

- I. DESIGN CONTROL: Facility, Staffing, and Assays for Mix of Health Care Problems.
- II. RAW MATERIAL CONTROL: Standards, Controls, Reagents, Instruments, Glassware, Specimens, Personnel.
- III. PROCESS CONTROL: Internal Program for Calibration, Process Control, and Preventive Maintenance; External Monitoring by Proficiency Testing and Inter-Laboratory Comparison Program of Accuracy and Precision.
- IV. OUTPUT CONTROL: Accurate Results in a Timely Manner and a Medically Significant Format.
- V. RELIABILITY CONTROL: Assay Utilization Correlates with Health Care Needs.
- VI. VERIFICATION CONTROL: Inspection and Accreditation, Workload Analysis; Cost Analysis.

Initially, with few parameters of testing procedures to select from, the physician found it relatively easy to select the proper test and method for a particular problem. The pathologist's time was devoted to searching for new parameters to investigate disease that could be easily done by laboratory staff and developing quality control mechanisms for Phase II and Phase III. Specifications were developed for chemical standards (bilirubin, cholesterol, cyanmethemoglobin). A system for process control at the bench was developed. Organizations

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became interested in survey of the "state of the art" of laboratory testing and how to improve it by further education and training of the pathologist and his technical staff.

Organized pathology devoted much attention to criteria for the educational requirements, training and certification of laboratory aids, technicians, and technologists. The criteria provided for education and training of generalists in medical laboratory technics. The specialty interest of technologists and their expertise developed with years of experience on the job and eventually promotion to supervisors in a particular discipline area. Relying on these experienced supervisors to bring problems for solution to his attention, the pathologist concerned himself mostly with those procedures that demanded his active participation, such as the interpretation of peripheral blood and bone marrow smears, problem body fluid sediments, tissue sections and cytologies. This daily routine allowed the pathologist to easily monitor many of the qualitative and quantitative tests associated with these procedures. The proper format for presentation of results to his physician colleagues for reliable interpretation of results was relatively simple due to the limited number of parameters available.

With the ever increasing variety of laboratory parameters and the volume desired by clinicians to resolve their patient care problems, the quality control of the flow of workload through the medical laboratory became more complicated. Yes, this necessitated the six phase management program outlined above. The new parameters required new instruments utilizing diverse physical principles in their measurement technics and marked diversification of reagents and growing dependency on industry to make them for the laboratory, frequently in the form of kits for a complete assay. Yes, overall quality control of the process was now being shared with the outside in-vitro diagnostic industry. Hence, the growing need for the Medical Device Act. The more complicated methods required additional personnel with Masters or Ph.D. degrees in their specialty areas, demanding new personnel requirements and working relationships and creating gray areas of supervision responsibility. Automation allowed the handling of increased volume of routine laboratory tests and the demand for some of the more sophisticated tests. With this mass production of results via automation, the necessity for computerization to aid in calculations and simply to just handle the volume of data being generated raised new questions of format of presentation of results to the physician for reliable interpretation of results to assure quality patient care. Should the format be decided by the ease of programming and economic cost or by the logical physiological groupings to aid interpretation in defining disease or monitoring the effects of therapy? Likewise, should data input require a new cadre of clerks and key punch operators to handle this via alpha-numeric terminals only? Or could instrument interfaces or terminals compatible with the bench technologists work be designed to allow their direct communication with the computer, thus maintaining their control of result reporting, but improving their productivity?

The automated profile testing to elicit hidden or unknown disease has evolved an attitude that the high volume production of accurate and precise numbers in Phase III is the practice of laboratory medicine. This has pinpointed the need for developing criteria or "standards" for the selection of the proper analyte and test method for a particular patient problem. Do you do 5, 10, 12, or 27 tests because they can be automated together for the sick and healthy? Yes, medical usefulness criteria for proper utilization of laboratory tests. The principles of mass production of industry can be applied to make possible the availability of accurate and precise numbers in high volume at a reduced cost. Of course, this is based on the assumption that the volume for these tests exists in a particular hospital or the test can be sent out to a regional laboratory to create the volume. The inspection and accreditation agencies in Phase VI now need to define criteria, not only for quality control of the result, but the necessity for doing a particular procedure on-site within a specified turnaround time to meet the physician's need for reliability in Phase V. Yes, individual

pathologists and their organizations will be interested in the further establishment of standards relating to all six phases of total quality control.

What will "standard" mean in each of these six phases and to each of the diverse people involved in or utilizing the medical laboratory. Even Webster's dictionary provides a diverse set of meanings for this term standard; for example, rallying point, personal emblem, criteria by authority, measure of quantity or quality by authority or legally fixed weight. The evolutionary history of the clinical laboratory field, as other industries, has led to diverse meanings for the term standard within the field.

TO INDUSTRY: Standardization provides a mechanism for dollar savings through mass production by production of uniform goods and reduction of time and materials through standard designs, equipment, procedures and testings. Opportunity for areas of profit if volume sales can be assured.

TO PURCHASING AGENTS: Standardization offers increased efficiency by freeing him from the need of preparing individual sets of specifications and descriptions for each purchase.

TO NATIONAL PROFESSIONAL TECHNICAL AND TRADE ASSOCIATIONS: Voluntary standardization allows them to bring their consumers' interests into consonance with current technology, engineering and manufacturing practices and laboratory and medical practices.

TO FEDERAL GOVERNMENT: As a vast business enterprise, standardization to them, is a mechanism to regulate government purchasing of commodities and services and fulfilling value objectives and standards for society.

TO PHYSICIAN CONSUMERS: Standardization means the availability of reliable laboratory results that are consistent day to day and from one institution to another.

TO THE NATION'S ECONOMY: Standardization pays off in greater profits, higher quality goods and customer good will.

TO THE WORLD: Standardization holds the key to the exchange of goods and services in international trade.

TO THE COMMON MAN: Standardization supports his belief in the nation's system of free enterprise to give him the best quality at the lowest reasonable price and, therefore, a higher standard of living.

To allow the development of voluntary standards for the medical laboratory in face of these diverse meanings for standards, the College of American Pathologists put forth the call in 1966 for the formation of the National Committee for Clinical Laboratory Standards. Working upon previous experiences of the CAP Standards Committee in the field and the success of consensus making standard agencies in other industries as follows:

Search within the science and practice should define the need for and probable basis for a standard to improve the quality of laboratory practice and, therefore, patient care. The basis for the standard would have to be tested by all interested parties within and outside the field - government, industry and professions. Analysis of the results and findings should lead to the narration of a set of specifications for a proposed standard, which must be announced to the clinical laboratory field. Time must be allowed to discuss the set of specifications through open forum and written communications among all parties involved. Justified criticism and suggestions could thus be obtained for analysis to lead to narration of a revised set of specifications, which should be annotated to define the standard. Verification of consensus of interested groups should document the specifications as a voluntary consensus standard for the medical

laboratory. Then comes the hard task of implementing that standard in the practice of laboratory medicine.

The implementation of the voluntary standard in the private sector is only assured when all interested parties in the consensus educate their personnel and apply the standard in their segment of the clinical laboratory industry. The implementation of these voluntary consensus standards should be so freely done and well done within the private sector that implementation by law and regulation is only a by-product of the voluntary effort when policing action is necessary.

Considering the great variety of standards needed in the clinical laboratory industry, have the interested parties agreed on a co-ordinating focus for developing consensus standards or should there even be consensus standards for certain areas (personnel, facility design, modes of practice)? Agreement on some consensus standards has been reached via NCCLS, others by regulatory action in the U.S. or pressure from international professional bodies. Some must be accepted as consensus standards as established previously for other industries via ASTM or ANSI. There is a need for agreement for NCCLS as a focus for defined types of necessary standards for the clinical laboratory industry. In turn, a liason must be established with ASTM for those standards overlapping various industries and with ANSI as the acceptance focus for U.S. consensus standards. From ANSI, U.S. standards could then proceed to various international bodies depending upon their types and international interests to be obtained. Yes, whither go biomedical consensus standards - to I.S.O., W.H.O., or international professional groups.

LCS 340:70:880

VOLUNTARY STANDARDS IN LABORATORY MEDICINE

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This is a summary of the paper to be presented by Dr. Keitges at the American Society of Quality Control at the national meeting in Chicago, May 8th. The word "standard" has taken on significant new meaning and greater importance in health care delivery systems in the past few years. Because of various factors there is a need, and in some cases an assumption, for the dire need of standards in all aspects of laboratory medicine. This need, real and alleged stems from three major areas; scientific, legislative and industrial.

First, the scientific needs should probably be subcategorized in terms of clinical and theoretic. The basic message from the Aspen conference on the analytical goals and clinical chemistry sponsored by the College of American Pathologists was that analytical goals and clinical chemistry should be established in the terms of patient's care. The terms patient care, medical usefulness, clinical relevance are not clichés, as some would have us believe, behind which the medical profession protects its way of doing things. These are real considerations involving real patients with real problems. Systems exist as well as data by which we can define medical usefulness. More detailed systems need to be developed and more data generated, however, indicators do exist which have by and large been overlooked or chosen to be ignored. National proficiency testing systems for example contain large amounts of data reflecting tests used, reagents and systems used, sensitivity and specificity, and their apparent effect on the clinically useful ranges. Most professional organizations now have committee's delegated to medical usefulness and clinical relevance. Inspection and accreditation systems have sampled wide levels of performance in clinical laboratories. Regional quality control programs and national serum pools have been used to generate data which gives within laboratory comparisons over short and long periods of time as well as interlaboratory comparisons. It is only logical that those interested in standards in clinical laboratory medicine use the data in these systems as one of their tools. Due to the tremendous amount of time, money and human effort that must be expended to develop standards, it is imperative that the system establish medical need in terms of patient care and then priorities on this basis for the kinds of standards in which areas to be developed.

The second major impact has been legislative, although usually receiving most of the attention and print "up front" this area of impact must always be secondary to the scientific and medical need consideration. Be that as it may, it is clear from recent legislation and regulation that the FDA, NBS and CDC as well as many state health departments are requesting and attempting to develop standards, reference methods and improving laboratory performance. The certified laboratory improvement acts and the recent legislation concerning medical devices are classical examples of the phenomena. We must also recognize the impact of publicity. Daily, articles and presentations are appearing in periodicals and newspapers pointing out problems in the quality of clinical laboratory health care. It is unfortunate the number of times these articles are traced to inaccurate or incomplete information and data and in some cases no data at all.

Third, industry finds itself in the difficult position of being all things to all men. As a result, industry asks for certain standards by which it can meet the need but yet, remain fiscally responsible to maintain a profit motive which is healthy. To this end, one tool, the concept of parametric standards have arisen. This appears to be a system in which labeling would include information in a standardized form enabling the user to analyze the relative merits of a given product. The FDA has shown important interest in this concept.

There is one absolutely essentially common denominator upon which this need for clinical laboratory standards should be placed upon. Before the system forges forward in an almost pavlovian way and develop reference methods and materials for all circumstances, situations, and constituents there must be recognized the definite limit to our resources in terms of people, time and money. It is therefore self evident that the priority and medical usefulness concept be employed before these projects are begun. A recent definitive attempt to prevent just a sequence of events has occurred as a result of a conference on a national understanding for a national reference system in clinical chemistry, sponsored by many federal and private professional organizations along with industry and convened by the CDC in Atlanta in November of 1977. The results of this conference included an organizational component beginning with a dedicated effort to establish priorities based on clinical need and patient care. As a result of this priority setting effort standards, reference methods and materials would hopefully be developed in those areas where the need existed. Following this, these standards, materials and methods would be subjected to a validation and transferability process within the national reference system.

The system would also include a library for all communications and documentation of standards, methods and materials followed by a system which would monitor the effectiveness of these efforts in terms of their impact on clinical need and patient care. True, there is some element of time consumption in this process but good standards like a good wine require the tincture of time and maturity. The administration of this national reference system has been assigned to the NCCLS. The right step has been taken in the right direction it is now time for the professions, federal agencies and government to work, participate and cooperate to assume success.

LCS: 342:70:880

VOLUNTARY CONSENSUS STANDARDS IN A REGULATORY CONTEXT

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The purpose of this paper is to point out some of the differences between voluntary consensus and regulatory medical device standards and how these differences should be considered during the voluntary standards development process.

The Medical Device Amendments of 1976 (PL 94-295) draws a clear distinction between voluntary consensus standards and mandatory standards adopted by the Food and Drug Administration. The distinction between these two types of standards will affect the process by which standards are developed.

Because of the significant differences between voluntary consensus standards and mandatory standards, many voluntary consensus standards will not be acceptable for regulatory purposes or will have to be significantly revised to be used as regulatory standards.

Consequently, voluntary consensus standards organizations should clearly understand the differences in purpose and effect of voluntary and regulatory standards.

Many voluntary consensus standards express, in general terms, desirable technical concepts which establish a frame of reference for safety and effectiveness. While establishing this general frame of reference for voluntary purposes may be desirable, attempts to enforce strict compliance with such standards under regulation could impose severe or impossible conditions of compliance on both users and manufacturers. For example, some voluntary standards may include requirements not within the present state of the art or requirements so expensive that implementation would be impractical.

Voluntary consensus standards, by definition, do not require absolute conformance on the part of the manufacturer or user. Voluntary consensus standards that are later put through proper FDA procedures and become regulatory standards require strict compliance by the manufacturer or user in order to avoid criminal and civil liabilities.

Section 514 of the medical device law authorizes the FDA to promulgate regulatory standards only on attributes of devices that (a) should be subject to regulatory standards and (b) will help assure the safety and effectiveness of devices. Unless there is an identified or potential safety or effectiveness problem with one or more device characteristics, Section 514 would not permit a regulatory standard to be set.

Many voluntary consensus standards deal with attributes of devices that may not, in a regulatory sense, help assure the safety and effectiveness of devices. Consequently, their use for regulatory purposes, in terms of purpose and effect, would be inappropriate.

The word "standard" should be considered in its broadest context to include guidelines, protocols, practices and procedures, specifications, performance and design standards, test methods, and any other voluntary consensus documents that directly or indirectly could be used to impose safety and effectiveness requirements on manufacturers and users.

It is unclear at the present time exactly what use the FDA will make of voluntary standards. It is clear from a reading of Section 514 that a voluntary consensus standard could be used as the starting point toward

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the development of a regulatory standard. For this reason, voluntary standards organizations may wish to determine at an early stage whether standards development efforts are intended to result in documents that should or should not be used in a regulatory context.

The purpose of this paper is to point out that since voluntary consensus standards may become the basis for regulatory standards, voluntary consensus efforts should clearly document voluntary consensus standards with clear statements of rationale and scope so the documents intended only for voluntary purposes (where regulatory consideration of safety and effectiveness are not involved) will not be construed as potential regulatory documents.

For example, purchase specification standards agreed on by manufacturers and users should not generally be regarded as regulatory standards. To explain further, a specification standard reflects an understanding between a manufacturer and a user for certain products primarily for communication and convenience and not primarily for regulation of safety and effectiveness, except in a secondary sense.

The purpose of this paper is not to discourage voluntary consensus efforts. The purpose is to begin to draw a clear line between voluntary consensus documents and potential regulatory documents and to provide guidance and assistance to the FDA as they consider voluntary consensus documents which may or may not be used for regulatory purposes.

While the FDA must strictly adhere to the legislative authority outlined in the medical device law in reviewing, revising, and adopting voluntary consensus standards as regulatory standards, a clear understanding of the differences between the two documents and the reflection of this difference in the developmental process, clear statements of scope and rationale, and good communications will help avoid the adoption of voluntary consensus standards that were not intended to be used as regulatory documents.

I hope this paper makes it clear that responsible standards writing and approval can only be undertaken with a clear and full understanding of the Medical Device Amendments of 1976 (particularly Section 514) and its potential relationship to voluntary standards. There are many summaries of this law available and AAMI will send copies on request.

LABORATORY QC: DOCTOR, IS THAT RESULT ACCURATE?

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INTRODUCTION

St. Luke's is an acute care general hospital having over 500 beds and serving a metropolitan area. The clinical laboratories are staffed 24 hours a day seven days a week, by more than 250 people. In 1977, over one million determinations were performed. Approximately 50% of these tests were done in the Chemistry, Radioisotopes and Physiological Monitoring Laboratories.

This paper describes the quality control programs designed for these three laboratories. The programs in their computerized form have been in use since November 1972.

Any QC program designed for these areas must have as primary goals accuracy and precision of test results with a short turn-around time. The program must also be able to verify that the same determination performed on another shift by a different technologist using a different method and/or instrument will yield statistically similar results. The program in use documents control status by test, shift, instrument, method and date. No matter when the doctor orders a test on his patient, be it first shift on Monday or third shift on Saturday, he can be confident of the results. The answer he obtains reflects the condition of his patient, and thus is not a function of the abilities of the technologist performing the determination, the reagents, the instrument or the method used, and is what our program verifies.

INDUCTIVE QUALITY CONTROL

Industry uses various methods of QC based upon direct measurements and/or destructive testing. Clinical QC cannot use these methods. In addition to being unable to test the constituent directly, are the added problems of small sample size, sample deterioration, special handling necessary for preservation and pressures to produce results quickly in life and death situations.

The method we use is based upon inductive reasoning. Induction is an instance of reasoning from a part to a whole, from particulars to generals.⁽¹⁾ It has become common practice in well run clinical laboratories to incorporate various systems of controls, pools, replicates and/or split samples as part of their on-going quality assurance program. Each of these systems is based upon inductive reasoning. If the controls are running "in control," then the process is in control, therefore the results of the unknown specimen run in the same batch is also thought to be correct.

However, there are times when the control sample is considered out of control when in fact the process is in control. Or the reverse, there are times when the controls appear to be "in" when in fact the process is out of control. In actuality we can be wrong in both instances. But how do we know this?

There are also economic factors. Over control can become prohibitively expensive, and not enough control gives no assurance of precision or accuracy. How then, do we strike a balance that gives us assurance of the precision and accuracy of our results, has a short turn-around time and yet is economically feasible?

AN OVERVIEW

We feel that the system we have devised addresses all four areas of quality assurance: precision, accuracy, speed and economy. The program consists of four parts: 1. normal and abnormal serum controls in each run; 2. plots of the controls on modified Shewhart charts⁽²⁾; 3. analysis of variance (ANOVA)⁽³⁾ and 4. tabulation of the mean, standard deviation and upper control limit of the range for each test by method.

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Use of normal and abnormal control sera verifies both areas of medical concern. The Shewhart range and average charts satisfy the questions of precision and accuracy, and shows when we have method trends, drift and/or change. The ANOVA shows day to day and within day variation. The mean, standard deviation and upper control limit of the range list are quick checks on overall process.

Usually, two commercially prepared unassayed sera serve as control samples in each run. One control is in the normal range of the test and the other in the abnormal range. We contract for sufficient amounts of these pooled sera so one lot number is available to us for approximately 18 months. Two months prior to the end of a lot number we start assaying the new lot. This gives us time to obtain sufficient data for the calculations of means and standard deviation and the generation of the charts.

INPUT DATA

Data Card

All data generated are logged on specially designed 11 by 13 3/4 inch sheets lined as 80 column data cards. See Figure 1. The following column headings are used for identification on each chart: columns 1 - 6 test name, column 7 control designation, column 8 number of plot points per day to be used in the ANOVA calculation, columns 9 - 13 method, column 14 shift designation, columns 15 - 16 month, columns 17 - 18 are pre-printed with the date and columns 19 - 20 the year. The remaining 60 columns are used in groups of four for listing of control results. The words PLOT appear above columns 21 - 24 and 33 - 36. These are the results that are averaged and recorded on the Shewhart charts. Figure 1 shows that CL (chloride) is the test, 2 is the control designation and four pieces of data per day are to be used in the ANOVA calculation. The method is manual and the date December 1977.

The ANOVA program is written such that only those days with the designated amount of data are used in the calculation. Therefore column 8 is filled in after the data are recorded. This allows us to take advantage of this program feature. For example, looking at Figure 1, if we list 2 in column 8, 62 pieces of data would be used in the ANOVA, a 3 would put 93 pieces into the calculation, a 4 would put 120 into the calculation, a 5 would put 135 and a 6, 114 pieces of data into the calculation. Therefore, the best number in this case would be 5. It can be seen that the data sheets serve the triple function of a log for the QC data, at-a-glance check of control status and as data cards for key punching.

The computer program that has been developed to produce our system is a result of the combined ideas of Riddick, Storey, Banker and Eichelberger⁽⁴⁻⁷⁾ with programming done by the Computer Center personnel at the University of Wisconsin-Milwaukee.

Shewhart Charts

We will describe the construction of the Shewhart range and average charts as this is a system routinely used in industry but rarely in the clinical laboratory.

When a new lot of control sera is being checked it is run along with the old lot, twice a day for 25 days, for each parameter checked. If the old lot is in control the value for the new lot is accepted and logged on a data chart. The sum (Σ), average (\bar{X}), and range (R) of each subgroup (k) is then calculated. Plotted points on our average chart are always the average of two individual control readings.

The following formulae are used in the calculation of limits for the average and range charts after the original data has been collected.

LEGEND

n = total number of observations
 Σ = sum
 k = number of subgroups
 X = each individual observation

FACTORS FOR CONTROL LIMITS

n	A_2	D_4	d_2
2	1.880	3.268	1.128

1. Average (\bar{X})

$$\bar{X} = \frac{\sum X}{n}$$

2. Grand Average ($\bar{\bar{X}}$)

$$\bar{\bar{X}} = \frac{\sum \bar{X}}{k}$$

3. Average Range (\bar{R})

$$\bar{R} = \frac{\sum R}{k}$$

4. Upper Control Limit of the Range (UCL_R)

$$UCL_R = D_4 \bar{R}$$

5. Estimated Standard Deviation ($\hat{\sigma}$)

$$\hat{\sigma} = \frac{\bar{R}}{d_2}$$

6. Upper Control Limit of Average ($UCL_{\bar{X}}$)

$$UCL_{\bar{X}} = \bar{\bar{X}} + A_2 \bar{R} \times 2/3$$

7. Lower Control Limit of Average ($LCL_{\bar{X}}$)

$$LCL_{\bar{X}} = \bar{\bar{X}} - A_2 \bar{R} \times 2/3$$

ST. LUKE'S HOSPITAL
MILWAUKEE, WISCONSIN
CHEMISTRY QUALITY CONTROL
V-200

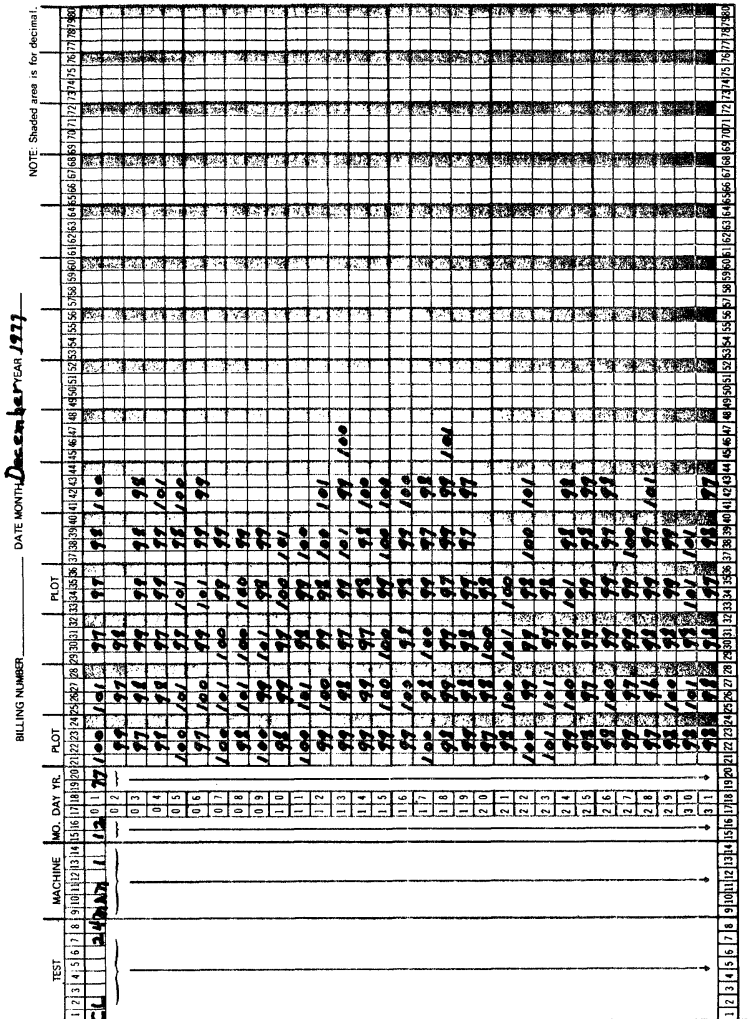


FIGURE 1 DATA CHART

QUALITY CONTROL CHART

TEST: CL 2 MACHINE MAN 1 DATE 12/77 LEVEL= 2 UNITS: MEQ/L

STD DEV= 1.286
STD ERR= .849
AVG= 98.79

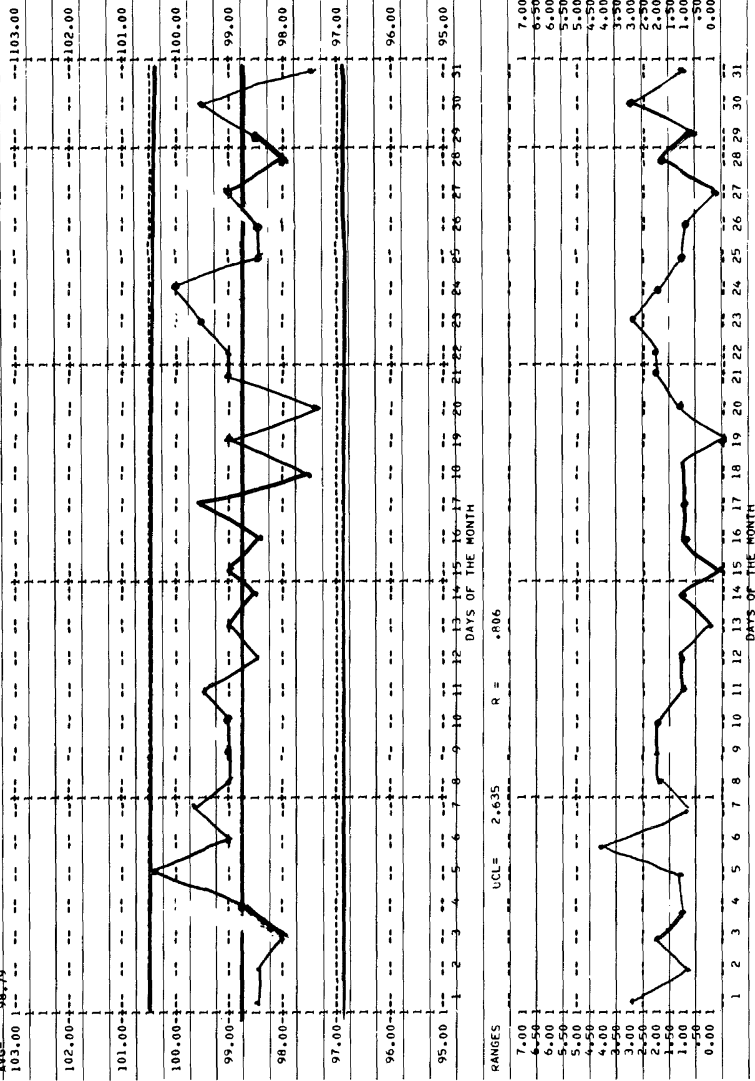


FIGURE 2 SHEWHART CHART

Figure 2 shows the Shewhart chart generated by the data in Figure 1. The chart heading gives the test name, control designation, method, shift, date, level and test units. The values for standard deviation (SD), standard error (SE), average, and 2 SE limits are preprinted on the average chart. The average range (\bar{R}) and upper control limit of the range (UCL_R) are preprinted on the range chart. Days for both the average and range are along the horizontal axis. Deviation from the mean and range respectively are on the vertical axis. All plotted points on the average chart are the average of columns 21 - 24 and 33 - 36 from the data card.

Control limits for the average chart are SE units because averages are plotted. The upper and lower control limits of the average are set at $\pm 2SE$ rather than $3SE$ because of the dire consequences if the process is out of control. This is a convention generally accepted in the clinical laboratory field. Plots falling in the $\pm 0 - 1.5 SE$ area are considered ok, those in the $\pm 1.5 - 2.0 SE$ area are in the watch zone, and those past the 2 SE limit line need action. The UCL_R is at 3 SD.

When the technologist checks an INDIVIDUAL control value it must be within $\pm 2 SD$ of the mean to be acceptable. The AVERAGE of the two plotted points must be within $\pm 2 SE$ of the mean.

OUTPUT DATA

Each test for which data have been submitted receives the following printouts: 1. A plotted range and average chart; 2. A blank range and average chart with limits generated from the submitted data; 3. An ANOVA table; and 4. A table giving that month's results by test, method, mean, SD and UCL_R .

DATA FOR TEST CL 2 MACHINE MAN 1 DATE 12-77

ANALYSIS OF VARIANCE TABLE

SUM OF SQUARES	DEGREES OF FREEDOM	MEAN SQUARE	F-RATIO	SOURCE
313.0000	120			TOTAL SUM OF SQUARES
143.0083	1			CORRECTION DUE TO \bar{X} OF 98.9075
169.9917	119			CORRECTED TOTAL SUM OF SQUARES
56.2417	29	1.939	1.568	DATE
6.0917	3	2.031	1.642	TEST
107.6583	87	1.237		RESIDUAL

TEST	MEAN	FREQ	TEST	MEAN	FREQ	TEST	MEAN	FREQ	TEST	MEAN	FREQ
*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
TEST1	98.70	30	TEST2	99.27	30	TEST3	98.73	30	TEST4	98.93	30
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----

GRAND MEAN	FREQ
*****	*****
98.9075	120
-----	-----

STANDARD DEVIATION

1.112

FIGURE 3

Figure 3 shows the ANOVA table generated from the data. Test identification is on the top. Then the usual ANOVA table showing the sum of squares, degrees of freedom, mean square, F ratio and source is displayed. Below this is given the mean and frequency of each column followed by the grand mean and SD.

TEST SUMMARIES					
TEST NAME	MACHINE	MEAN	ST. DEV.	RANGE UCL	
SAL 2	GAS	23.0	.206	.221	
SGOT 1	SMA	34.1	2.052	4.638	
SGOT 2	SMA	103.1	4.214	9.171	
SGOT E	ACA	335.9	5.143	11.912	
SGOT N	ACA	24.7	.977	3.268	
SGPT E	ACA	133.8	1.740	0.000	
SGPT N	ACA	29.3	.890	0.000	
TRIL 1	ACA	1.5	.076	0.000	
TRIL 1	GAS	1.5	.050	.042	
TRIL 2	ACA	4.7	.154	0.000	
TRIL 2	GAS	4.7	.164	.084	
TRPC 1	ACA	376.3	5.023	0.000	
TP 1	ACA	7.0	.059	0.000	

FIGURE 4

Figure 4 shows a portion of the test summary. These data are transferred to individual test summary sheets as in Figure 5. These sheets are useful for checking the ongoing capabilities of the process.

Test:

Method:

Control:

DATA FROM	MEAN	STANDARD DEVIATION	RANGE LIMIT

FIGURE 5

INTERPRETATION

One of the first considerations in setting up the range and average charts was the subgroup size. Duncan⁽⁸⁾ considers nothing more important. The samples on the control chart should represent subgroups of output that are as homogeneous as possible. They should be such that if assignable causes are present, they will show up in differences between the subgroups rather than in differences between the members of a subgroup. We chose two as our subgroup size because this number of test runs are performed within a short period of time on each shift. This is the same reason underlying the maintenance of separate charts for the same test done by different methods on different shifts.

The average chart is the graphic representation of the accuracy of the process. Figure 6 shows normal randomization of points around the mean. One or more points falling at or beyond the 2 SE limits need investigation. A run of 7 or more points going up, down or running on one side of the center line, indicates a trend or shift respectively. Figure 7 illustrates a process that is trending. Figure 8 shows a process that has shifted. In all instances the plot points are within the control limits but are showing process problems or changes. Cycles or other nonrandom patterns in data also need investigation.

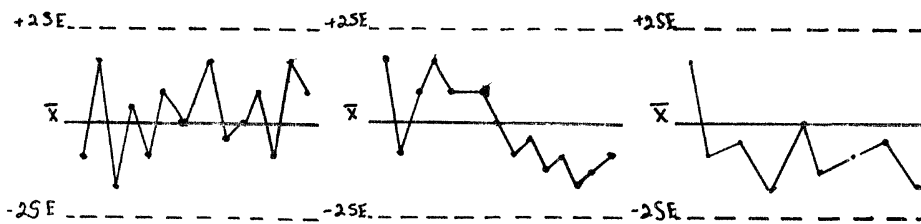


FIGURE 6

FIGURE 7

FIGURE 8

The range is the graphic representation of precision. If the average plot is in control but the range is not, there is need for investigation.

The ANOVA is the summary of variation both within days and between days.

ADVANTAGES

(9) There have been arguments pro and con for the use of ANOVA versus control charts. We find the combination of the two to best serve our needs. The control charts are a visual device. Even personnel with little grasp of the underlying QC principles can read them and understand when an out-of-control situation exists. These charts are excellent for current process control.

The ANOVA gives an overall idea of how a process is performing. It gives a maximum amount of information on limited amounts of data. This can be useful when considering introduction of a new method.

Approximately 170 individual tests are charted monthly. Computerization of the system has shortened chart preparation time considerably. Calculation of ANOVA's for this volume of tests is an added statistic not possible when done by hand. The original cost of programming and the ongoing cost of keypunching and computer time is well offset by the time saved and the documentation produced. Thus, we satisfy ourselves, the clinicians, and our accrediting agencies of the quality of the results produced.

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SNOMED ENHANCEMENT OF MAN/MACHINE MEDICAL AUDITS

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MOTIVATION

The need for quality of care evaluations (Medical Audit) and for cost control (utilization review) has become of increasing importance in recent years. This is especially true because of the increasing role of third party payors especially the various governmental programs. Utilization review concentrates primarily on the length of stay for various illnesses and the Physician must certify that extension in time is based upon patient needs. Each Hospital staff under rules of the Joint Commission on Accreditation of Hospitals (1) must have a committee which provides an audit function on the length of stay of hospitalized patients. More recently Public Law 92-603 (2-3) contains provisions for the establishment of Professional Standards Review Organizations, or PSROs, which examine the standard of care provided to hospitalized patients. While formalized by Federal Legislation in the 1972 law for PSRO Medicine had already taken the lead in studying its own practices by introspective review and most medical audits of today include useful items not actually demanded by the law itself or subsequent regulations.

THE SYSTEM

A variety of different audit approaches have been advocated. Despite the varying needs all existent systems have common data items. Additional items may be unique to one system or need. The MAN/MACHINE Medical Audit system described herein combines a number of these data items into one scheme which can then be used for more than one purpose.

Those items needed to accomplish a desired audit include at least the following categories:

1. Demographic Data;
2. Indications for admission and date;
3. Diagnoses and date of establishment;
4. Medical procedures and date performed;
5. Complications and date of occurrence;
6. Indications for discharge and the date of discharge;
7. Disposition of the Patient and destination after discharge;
8. Detailed charges.

Some of these data items are handled similarly in a number of approaches stretching from completely manual systems all the way to completely computerized systems. Many of the data items can only be handled by utilizing coding schemes to express otherwise unwieldy or even unintelligible information. Design of coding systems, to be useful, must have provided codes for all of the categories which must be machine processed. Many existent codes may be used for medical diagnoses and complications including HCDA II, ICDA-8 and the Systematized Nomenclature of Pathology (SNOP). A new code to be introduced in January 1979 is ICD-9-CM which will also provide procedure codes in addition to diagnoses and complications. The American Medical Association also has a procedure scheme called Current Procedure Terminology IV or CPT IV. (codes are discussed extensively in Ref. #4) The newly introduced Systematized Nomenclature of Medicine (5) has been designed to provide code numbers to all the required fields necessary to computerized auditing including many categories not available in other systems. The multifield concept and

thoroughness of SNOMED have given it superiority as the code system of choice for all auditing purposes by computers.

CRITERIA SETS

The next common step after choosing the data items and choice of the coding system for use is to develop appropriate sets of criteria for the various medical conditions. By grouping diagnoses into broad categories, each represented by a unique criteria set, the complexity and size of the final system is reduced. This step involves the creation of medical committees in the various specialties to derive suitable criteria each in their own area of expertise. An example of the result of this task is the "Inpatient Medical Care Criteria" manual developed by the Pennsylvania Medical Society in conjunction with the Hospital Utilization Project.⁽⁶⁾ Needless to say, this activity is peer-oriented, performed by medical professionals. In addition, it is expected to be an ongoing function, since advances in medical science will modify the professional standards to be applied in assessing health care. An estimated two hundred criteria sets will cover 90-95% of all admissions in a general acute hospital.

Although the criteria sets are formulated primarily for quality control, they may also include billing information to determine the economic impact of alternate treatments. Three components make up the established criteria set:

1. List of Diagnoses which will fall under the set;
2. List of Audit Items which are to be collected and assessed in order to perform the audit;
3. A representation of the valid combinations representing acceptable health care.

In the Medical Audit System, (1) and (2) are represented by codes which can be translated back into English as necessary. The valid combinations of audit item values are represented through Acceptability Masks, each mask standing for a unique combination of audit items which are considered satisfactory for treatment under the criteria set.

Determining the techniques to be used in collecting data values for the audit is step four in design of the Medical Audit System. As much as possible, existing automated sources in the institution should be relied upon. This ensures timeliness, accuracy, and consistency of data, as well as reducing redundancy of collection procedures. Few hospitals, however, will have all the necessary information already available in machine-readable form, however, and none will have it formatted and structured in the ideal fashion for audit purposes. Final decisions in this area will also be affected by future plans of the hospital toward automating medical data.

As the values of audit items for a case are collected, an Audit Compliance Mask is built up for each diagnosis. This mask, created to make it compatible with the Acceptability Masks for the criteria set covering the diagnosis, indicates whether or not each audit item was satisfactorily performed.

Lastly, and most importantly, the audit procedure itself must be formulated. The basic assumption made in establishing a medical audit system, that all cases treated at a hospital are subject to review by suitably qualified peers of the health care providers, is extended in the Man/Machine Medical Audit System. Rather than requiring every case to be manually audited the criteria set information is automated and the majority of cases are handled by a machine audit. Then the only cases which must be man-audited are those for which suitable criteria sets have not been formulated, and those which, for some reason, fail to pass an established automated criteria set. This basic system concept solves the primary problem seen with medical auditing in a strictly manual mode: the vast amount of professional time required to accomplish the audits.

The audit algorithm itself should be simple, universal, and amenable to manual performance. In the Man/Machine Medical Audit System, the algorithm consists of comparing the Audit Compliance Mask built up for each diagnosis in the case to the set of possible Acceptability Masks defined for the relevant criteria set. This comparison is done using simple logical operations built into all computer systems and available in most programming languages. The result is a definite pass or fail, which can be displayed with relevant information about the case, as desired by the committee in charge of the review process.

Medical auditing can be ongoing or retrospective. For the purpose of compiling information for federal P.S.R.O. use, a retrospective audit is sufficient. Depending on the degree of hospital commitment, however, the system should be evolutionary, and capable of being used for continual auditing during the patient's stay.

DATA ITEMS

The following twenty data items include all of the above listed categories deemed necessary to perform a useful audit:

#001	Personal Identification Code	
#002	Date of Birth (mo-day-yr)	
#003	Sex (M-F)	
#004	Race (Collected after admission)	
#005	Residence (zip)	
#006	Hospital Identifier	
#007	Admission Date (mo-day-yr)	
#008	Discharge Date (mo-day-yr)	
#009	Attending Physician (Regional #)	#109-209, etc. consultant, etc.
#010	Operating Physician (Regional #)	#110-210, etc. additional surgeons
#011	Diagnoses (Any code system)	#111-211, etc. final diagnoses
#012	Procedures - Dates	#112-212, etc. extra procedures
#013	Disposition of Patient	
#014	Expected Source of Payment	

PSRO Additions Needed to be in Compliance

#015	Detailed Charges	- #015 - Lab
		- #115 - XRay
		- #215 - Pharmacy
		- #315 - Other Services
#016	Class of Admission	

Audit Additions Which Allow the Quality of Care to be Better Assessed

#017	Complications	#117-217-317, etc. additional complications
#018	Indications for Admission	
#019	Indications for Discharge	
#020	Audit Diagnostic Class (200)	

By taking various combinations of data items various questions can be answered. Length of stay is based upon comparisons of admission and discharge dates. While this appears to be relatively simple to do visually it is also a good example of data which probably already exists in machine readable and processable form in most Hospitals so that the computer can easily be programmed to go the extra step and provide an actual automatic calculation and printing of the result.

Example: Medical Audit for Appendicitis

Appendicitis is a surgical condition which may be logically analyzed as might be derived from a typical record.

A) Indications for Admission

1) Typical History including:	Nausea and Vomiting	F-61640
	Anorexia	F-60014
	Right Lower Quadrant Pain	T-Y4120 F-82609
2) Typical Physical Findings:	Rebound Tenderness	F-82610
	WBC > 11,000	T-2945 > 11000
	Fever (Oral) > 100°	F-03003 > 100

B) Type of Admission

- | | |
|-----------------------------------|--------|
| 1) Emergency Admission Acceptable | P-0030 |
| 2) Elective Admission Acceptable | P-0021 |

C) Pathologic Diagnosis

- | | |
|--|----------|
| 1) Positive for Acute Appendicitis | T-66 M-4 |
| - if Positive A1 and A2 above may be Negative and pass the audit. | |
| - if Negative Pathology the A1 and A2 must be present to pass the audit. | |

D) Pre-Op Hospital Services Required

- | | |
|------------------------------|--------|
| 1) Complete Blood Count Done | P-2814 |
| 2) Urinalysis Done | P-4150 |

- if these were not done the case fails the Audit

E) Pre-Op Hospital Services Acceptable for this Diagnosis

- | | |
|--------------------------------|---------------------------|
| 1) Fasting Blood Sugar | T-0X P-4020 |
| 2) Urea Nitrogen or Creatinine | P-4020 F-10460 or F-11390 |
| 3) EKG if over 35 years old | P-7110 |
| 4) Chest X-ray | T-Y21 P-X000 |
| 5) X-ray of Abdomen | T-Y41 P-X000 |

- Procedures other than above must be explained before payment is made.

F) Expected Length of Stay

- | | |
|--------------------------------|--------------|
| 1) One Day Pre-Operative | (Calculated) |
| 2) Post Operative up to 7 days | (Calculated) |

- These are calculated from admission, operative and discharge dates.

G) Complications Extending the Length of Stay

- | | |
|----------------------------|-------------|
| 1) Peritonitis | T-Y44 M-4 |
| 2) Wound Infection | M-14010 |
| 3) Pneumonia | T-28 M-4 |
| 4) Phlebitis | T-48-49 M-4 |
| 5) Abscess | M-4174 |
| 6) Urinary Tract Infection | T-69 M-4 |

- Complications automatically extend acceptable Length of Stay.

H) Indications for Discharge

- | | |
|--------------------------------|---------|
| 1) Patient Ambulatory | P-0105 |
| 2) Afebrile < 99° for 24 hours | F-03001 |
| 3) Full Diet | E-X030 |
| 4) Alive | F-00101 |

- Acceptable for discharge if all the above are present.

N.B. Since SNOMED is carefully designed as a hierarchical code in which each digit is significant the above fields are truncated as the computer search would be. Example: M-4 is a totally inclusive search algorithm which contains any and all the variable ways of specifically coding an inflammatory process. Five full digits are available such as: Multifocal Fibrocaseous Inflammation M-45273. This descriptive term would still satisfy the audit criterion of "inflammation" and would be picked up correctly by the simple search algorithm "M4". Note that in the Procedure (P) and the Function (F) fields the full numbers available are usually necessary to adequately specify that P or F concept.

GENERAL CONCEPT OF THE AUDIT SYSTEM

The general approach of this Man/Machine Audit is to develop a series of criteria which will cause a case to be acceptable to the audit committee. This "criteria set" must include some flexibility to account for any acceptable alternatives for cases. These are stored item by item in a set identified with each disease.

When an audit is to be performed the system collects the audit items on a specific case in proper order and compares these item by item with the "criteria set for this diagnosis. If each item is acceptable according to the criteria set the case passes the machine audit".

If any single item fails to match and to prove acceptability then the case fails the machine audit. The criteria item or items are automatically listed to direct the attention of the audit committee to that item for their visual review.

It must be stated that the committee establishes the criteria set it will accept in the first place. Thus it may be said that any case passing the machine audit has in truth really passed the manual (committee) audit. The goal of the committee is to select a criteria set which will minimize the number of Machine rejected cases and yet criteria will be defensible to other physicians as reasonable and proper. It must be remembered also that "failing" the machine audit only means that it must be individually scanned by the committee not that there will be predictable failure of the manual audit. The variability of cases within acceptable practice limits is quite broad. It is a reasonable goal if the committee can raise the audit criteria set to the level that 95% of cases can be automatically handled with only 5% of the cases requiring special discussion.

SUMMARY

The general need for evaluation of the quality of medical care has been discussed. Most of the data items needed to provide the audit function under control of the Medical Staff are gathered routinely by the hospital's own medical record keeping and accounting functions. The additional items required of a medical nature can be accumulated as a byproduct of other medical activity. It is explained that the Systematized Nomenclature of Medicine (SNOMED) is the only coding system sufficiently detailed to allow the computer to compare actual patient care with predetermined norms established by the Medical Staff and stored in the computer. Individual case analyses can then be gathered into statistical groupings for disease by disease analysis. The automated machine audit is an extension of a manual audit which would otherwise have to be performed on each case. Early experience suggests that approximately one case in twenty, or less, will require committee inspection.

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APPENDIX

Example of Single Case Audit which Passed the Audit

MEDICAL AUDIT SYSTEM REVIEW OF FIRMIN DESLOGE HOSPITAL

CHART NUMBER 69-1091	ADMISSION TYPE 2
HOSPITAL CODE 01	REFERRAL SOURCE 1
BIRTH DATE 8/5/50	ADMISSION DATE 2/3/78
ZIP CODE 63113	DISCHARGE DATE 2/9/78
SEX F RACE 2	DISCHARGE STATUS 1
PAYMENT SOURCES 6	DESTINATION
PRIMARY ATTENDING PHYSICIAN	9426 SPAFFORD,
PRIMARY OPERATING PHYSICIAN	9426 SPAFFORD,
SECONDARY OPERATING PHYSICIAN	9754 WILLMAN, VALLEE L

DIAGNOSIS 0004510000 PRIMARY APPENDECTOMY
ESTABLISHMENT DATE 2/3/78 OPERATION DATE 2/9/78
TERMINATION DATE 2/9/78

ITEM	VALUE	RANGE
2 NO COMPLICATIONS		
3 AFEBRILE (LT 99.6 FOR 24 HOURS)		
4 AMBULATORY		
5 FULL DIET		
6 ALIVE		
7 TOTAL LENGTH OF STAY	6	2 7
8 POST-OPERATIVE LENGTH OF STAY	0	0 7
31 HX DESCRIBES RIGHT LOWER QUADRANT PAIN		
32 HX DESCRIBES REBOUND TENDERNESS		
33 HX DESCRIBES NAUSEA, VOMITING, ANOREXIA		

LCS 710:70:880

QUALITY CONTROL IN A HEALTH INFORMATION SYSTEM

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INTRODUCTION

Awareness of the need for accurate data in health information systems has increased in recent years. New emphasis is being placed on the quality of the coding and abstracting of information obtained from patient medical records, and on the adequacy of controls and audit procedures used in data processing.

Data quality has long been the concern of the Commission on Professional and Hospital Activities (CPHA)*. The PAS System, centered around CPHA's main program, the Professional Activity Study (PAS), is a medical record information system that currently processes over 17 million discharge abstracts per year from over 2,200 U.S. and Canadian hospitals. Hospitals that participate in the PAS System record on one-page preprinted documents the data abstracted from the medical record of each patient and mail these documents to CPHA where they are computer processed. Hospitals receive routine and special reports as part of their participation in this system.

CPHA's data quality control activities in the PAS System can be grouped into two major categories:

1. that related to the quality of coding and abstracting done by the hospitals, and
2. that related to the processing of the data from approximately 65,000 abstracts received each day. In particular, specific attention is paid to the quality control of data accuracy, completeness (complete in that the system contains all the records it should), security, confidentiality, and timeliness.

This paper addresses CPHA's quality control activities in both areas.

QUALITY CONTROL OF CODING AND ABSTRACTING

Traditionally, medical record department personnel coded a patient's diagnoses and operations as a means of retrieving the records according to their subject matter. More and more, coded data are becoming the foundation for statistical reports which are used to make decisions in the management of the health care industry. Today the uses of statistics gathered from the information in medical records are vast. For example, coded data are often used to

assess the quality of patient care,
set priorities for improvement of patient care,
assess the utilization of facilities, and
determine reimbursement rates for insurance claims.

The new applications of these data have increased the importance of coding accuracy. (1) And the users, in order to make well-informed decisions, need quantitative measures of the accuracy of the data upon which they are basing those decisions.

*Located in Ann Arbor, Michigan, CPHA is a nonprofit, noncommercial, and nongovernmental research and education center dedicated to the improvement of hospital and medical care.

The first significant documentation of coding accuracy was obtained through a study conducted by the Institute of Medicine, a division of the National Academy of Sciences.⁽²⁾ In that study, conducted in 1975 and published in 1977, the level of reliability in the coding of principal diagnosis (the final diagnosis most responsible for occasioning the patient's admission to the hospital) was 65%. This result makes clear the need for both raising coding accuracy and developing quality control procedures to guarantee that the coding of data is at a level of excellence.

CPHA recognizes that the first step in producing reliable statistical reports is to ensure that the coded and abstracted data coming into the PAS System are as accurate as possible. The Commission, therefore, shares with the hospital the responsibility for acquiring quality data and meets this responsibility by providing an easy-to-use abstract, detailed reference materials, training and consultation, and methods for evaluating coding and abstracting performance.

PAS Case Abstract

Each hospital in the PAS System is supplied with abstracts that have been carefully designed to promote the accurate recording of data. The abstract is a computer-scannable document with a mixture of bubble mark-offs and hand-formed characters.

Training and Consultation

At the time a hospital begins participation in the PAS System, it enters into an intensive training program. A CPHA representative phones the chief of the medical record department and schedules an in-person visit to the hospital. Together they review all the reference materials sent to the hospital including the PAS System Manual,⁽³⁾ a manual of over 100 pages containing detailed instructions and illustrations⁽⁴⁾ for completing each abstract item, and a programmed instruction manual⁽⁴⁾ for coding from the Hospital Adaptation of the International Classification of Diseases, Second Edition (H-ICDA-2)⁽⁵⁾ used in converting all diagnoses and operations into numeric codes.

CPHA then assigns a coding specialist and a liaison representative to train and consult with each hospital. During the training period the hospital enters on the abstract both H-ICDA-2 codes and the English terminology for all diagnoses and operations. The abstracts are sent to CPHA and checked for accuracy by the coding specialist. During a typical month, CPHA's coding specialists examine more than 40,000 abstracts submitted by training hospitals. In addition, telephone conferences take place to review coding and abstracting principles.

When a hospital has completed abstracting all the discharges for its first month's data, its PAS System reports are generated. One set is sent to the hospital and one set is produced for the hospital's liaison representative who checks the reports for inconsistencies that could indicate systematic coding or abstracting problems. A telephone conference is then held with the personnel at the hospital to review any problems. At this time a report review is also conducted by CPHA staff to familiarize medical record personnel, administrators, and medical staff with the kinds of data they will receive routinely and the ways in which these data can be effectively used by the hospital.

The training period ends when the hospital has reached an acceptable level of coding accuracy and has demonstrated a good understanding of the PAS System reports. The liaison representative continues to act as a consultant to the hospital in resolving any future questions or problems. If the medical record department feels retraining is in order, for example, because of personnel changes, it may request to be returned to training status.

Evaluation of Coding and Abstracting Performance

As mentioned above, the reports themselves are a valuable tool for determining data accuracy and completeness. The more the data are used, the higher the level of accuracy. To stimulate report use CPHA continually conducts education sessions that encourage better quality control of input and provide practical applications of PAS System data. Hospitals are urged to review their reports and submit the necessary corrections if any errors are discovered.

CPHA has developed a new method of quality control for assuring coding accuracy that applies principles long used in industry. This quality control method is designed to help detect and correct procedural or systematic errors in the coding process.

The method is based on the following five steps in the quality control process:

1. Establish criteria (set standards for defined parameters).
2. Measure performance.
3. Analyze deviations.
4. Take action.
5. Follow up.

CPHA has published a monograph entitled Quality Control of Diagnosis and Procedure Coding⁽⁶⁾ which describes the quality control method, presents specific criteria for assessing coding accuracy, and provides a means for applying the method, the Quality Control Worksheet for Coding. The worksheet guides the user through the five steps of the process and provides for recording the results of each step. Upon completing such a quality control study, the medical record department supervisor will know not only whether errors are occurring, but also why they are occurring and what plans can be implemented to correct poor performance.

The use of a quality control process employing objective criteria, with statistical standards for accuracy against which actual performance can be measured, represents an effective and efficient method for controlling and improving coding accuracy. More importantly, a mechanism is provided to detect and ultimately eliminate the causes of error.

QUALITY CONTROL IN PROCESSING PAS DATA

Once the hospital submits its patient information to CPHA for processing, numerous control techniques are applied throughout the PAS System to maintain data quality and produce reliable statistical reports.

Processing of Batches

As a method of document control, abstracts are usually batched into groups of 50 or 100 by the hospital. All batches contain abstracts only for patients discharged from the hospital in the same month. Accompanying every batch is a batch cover sheet containing the hospital's identifying number, batch number, discharge month, and the number of abstracts within the batch.

Upon receipt of a batch at CPHA, the first and last abstracts are verified against the information on the batch cover sheet. The batches are inspected for the presence of other documents, such as correspondence inadvertently interspersed with the abstracts. Document control begins immediately in that all the information contained on the batch cover sheet is entered into the computer the day the batch is received.

The hospital continually submits batches of abstracts as they are completed. The medical record department maintains a control report by discharge month for batches and abstracts mailed and a stub from each abstract with the patient's number, batch number, and page number within the batch. When the hospital sends the last batch for a month, it also encloses a form notifying CPHA that abstracts have been completed for all patients discharged in that particular month. The "closing" hospital is given priority in processing.

Optical Scanning

After a batch of abstracts has been inspected, it moves to the next phase in the PAS System: being electronically read by an optical scanner and stored on computer media. All information on the batch cover sheet and on the abstracts is scanned. The entire batch is rejected if there is any discrepancy between the information read from the batch cover sheet and the information originally entered into the computer the day the batch was received. When the abstracts are read, they are also counted. After scanning is complete, a control report is produced

indicating the total number of abstracts recorded on the cover sheet and the total number of abstracts read by the scanner. If batches are received out of sequence, a second control report will indicate a missing batch.

As a continual check on scanner accuracy in reading bubble mark-offs, a batch of test abstracts is scanned every two hours. Test output is compared against the actual entries on the abstracts. If there is a discrepancy between the two, the abstracts and the data tape of all batches run since the last scan test are held, the scanner is realigned and the test batch rerun. When the test output and the abstracts are in agreement, the held batches are rescanned and a corrected tape is produced.

Scan Verification

Due to individual variations in handwriting, the hand-formed characters scanned from the abstract and the batch cover sheet are independently re-entered into the computer system. Data entry operators key-verify approximately 65,000 abstracts a day using cathode ray tubes (CRT) on-line with CPHA's main computer. The operator enters the data directly from the abstract. This information is displayed on the screen immediately in front of the verifier. If a difference occurs between the keyed data and the scanned data, the screen flashes back that a discrepancy has taken place. The operator re-enters the recorded value from the abstract to resolve the problem. If the verifier is unsure of the actual value, the abstract is flagged for further review. If necessary, the hospital is called to obtain the correct information.

The operator also verifies the data on the batch cover sheet. Again, if there is a count problem, the verifier makes the final determination as to the correct number. The hospital is always notified of any count changes, so that it can update its internal control counts and forward any missing abstracts.

Edit

After verification, the data from each batch automatically go through an editing process. The primary function of the edit is to detect any errors introduced during the verification process, for example, the presence of alphabetic characters in fields authorized for only numeric data.

Messages are printed for each patient record with an error. The error message is matched against the original abstract. If necessary, the computer record is corrected and the batch is again edited. If the error was not caused by scanning or by verifying the document, the error is left and the next step in the quality control procedure, the audit, will generate an audit error message which is sent to the hospital.

Audit

When editing is completed, the patient record undergoes an extensive quality check called the audit. Over 300 data consistency and completeness checks are made, for example:

1. completeness of all basic patient information, such as admission and discharge dates,
2. agreement between sex-specific diagnosis codes and the recorded sex, and
3. reasonableness of certain data items, such as patient weight of over 400 pounds.

The data are then transferred to a working computer file. All the hospital's patient records are now easily accessible ("on-line").

Another important result of the audit process is the computer-generated audit error message.

Computer-Generated Audit Error Messages

An audit error message is produced every time the patient record fails an audit check. Approximately 5% of all abstracts generate audit error messages. A data control technician compares the error found to the original abstract item to determine if the error was introduced during processing. If it was, the correct information is entered into the system. Coding problems detected by the audit are forwarded to CPHA's coding specialists. Errors not correctable at CPHA are mailed to the hospital. To minimize the possibility of additional problems, the audit error message contains all the information recorded on the patient abstract. The hospital enters the correct data directly on that form before returning it to CPHA.

Corrections and Supplemental Information

A hospital can also generate its own corrections by adding information omitted from the original abstract and by changing or deleting data currently recorded on the abstract. Information which would not fit on the abstract, such as additional diagnoses, operations, or optional data (data defined by the hospital) is submitted as supplemental information to CPHA.

Corrections and supplemental information are entered by a CRT onto the working file. As the data are being entered, an abbreviated version of the audit takes place on the items being applied. Corrections are not accepted by the system if this check detects a problem. An error message flashes on the screen. The operator determines if a true error exists and, if so, copies the message onto the correction or supplemental form, and returns it to the hospital for action.

The hospital may submit corrections and supplemental information until all its abstracts have been processed for a calendar semiannual period.

PAS System Control Files

Several control files oversee the entire PAS System: the batch and report control files, and the hospital identification file. The batch control file keeps track of each batch as it goes through the various processing steps. A batch cannot go on to the next step unless all prior processing steps have been completed. The report control file indicates when a hospital's data are ready for report production.

The hospital identification file sets hospital-specific values used in the audit, such as definitions of the hospital's clinical services and optional data. This file also governs which reports are generated and their frequency.

The hospital identification file as well as the batch and report control files are accessible on the CRT for reference. These displays inform authorized personnel as to the status of an individual patient record, a batch, or a report. With this information readily available, it is used for data quality investigations.

Report Controls

Standard PAS reports are produced for monthly and semiannual time periods. When the hospital notifies CPHA that abstracting is finished for a period, the "closing" hospital is given priority throughout the PAS System. Any outstanding batches are scanned; all corrections and supplemental information that have been received are applied; the data are edited and audited. Batch and abstract counts on the working file are compared to the corresponding information on the hospital's closing notice. No reports can be processed until these counts are reconciled.

Once the working file has been updated and all counts justified, the reports are produced. Generally CPHA processes and mails monthly reports back to the hospital within 48 hours after receipt of the closing notification. Once the semiannual reports have been processed, the data are transferred to permanent file storage and become a part of over 150 million hospitalizations contained in the PAS data library.

Report Inspection

All PAS reports are inspected for usability, accuracy, and internal consistency prior to mailing. If printing is smudged, off-line, or omitted, or any pages are torn, wrinkled, or missing, the reports are run again. Independent control reports are generated indicating total patients processed for the hospital's report. These control counts are compared against the actual totals found on the hospital's report. Any detected problems are referred to the Quality Control Department for research and resolution.

Quality Control Department

Because all of CPHA's data processing is contracted to Electronic Data Systems (EDS), the role of the Commission's Quality Control Department (QCD) is essential in assuring the quality of data being processed. The QCD participates in setting system performance standards, monitoring the performance in relation to those standards, investigating PAS System problems when they arise, making recommendations to management when performance is below the standards, and developing new ways to improve the quality of data.

To maintain control of all PAS System changes, the QCD has designed data files which are used for testing all new subsystems and any program changes. This final testing ensures that the entire PAS System continues to operate as intended.

PAS System Security

Security measures are employed within the PAS System not only to guard against theft or improper access to the data, but also to provide recovery capability for lost or damaged data. The problems of maintaining data security are compounded by the complexity of the PAS System and the large volume of data moving through that system. Security procedures pertaining to recovery capability include maintaining copies of all data files and all programs and control files used in each processing step. These serve as a back-up and enable CPHA to automatically recover data marred by a software or hardware malfunction. Back-up programs and control files critical to system operation are updated weekly and stored at an offsite location. Twenty-four hour physical plant security is enforced. In addition, there is limited access to specific areas within the building, such as the computer room and the tape vaults containing the back-up files.

Confidentiality of PAS Data

The usefulness of PAS data for research and planning has prompted numerous requests for studies by member hospitals and outside organizations. CPHA recognizes the potential of PAS data while maintaining a strong commitment to the strict confidentiality of all data submitted by PAS hospitals. The contract between CPHA and client hospitals stipulates that CPHA will not divulge the identity of a hospital included in any report, publication, or study. If the identity of a hospital is required by a researcher, or if it can be deduced from the uniqueness of the data or the small sample of hospitals studied, a three-way written agreement between the hospital, the researcher, and CPHA must be made. The identity of physicians and patients cannot be divulged since CPHA is furnished only with hospital-assigned codes as identifiers.

It is emphasized to every CPHA and EDS employee that he is dealing with information of a confidential nature. All CPHA employees and all EDS employees assigned to CPHA's account must sign a policy statement acknowledging agreement on this subject. Under no circumstances may an employee of CPHA release any confidential information unless authorized by the president of CPHA. The identification of any hospital, physician, or patient by name or number in relation to any data passing through the employee's hands is forbidden.

Conclusion

CPHA is committed to having high quality data in the PAS System. Fulfilling this commitment requires having not only ongoing, systematic quality control activities, but also creative applications of quality control principles for the accuracy, completeness, security, confidentiality, and timeliness of the data in the system.

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A BUSINESS SYSTEMS APPROACH TO GMP'S
A Guide to the Small and not so Small Medical Device Manufacturer

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AN INTRODUCTORY SCENARIO

Company X has been manufacturing medical devices for some time. Customers are generally satisfied with their products. There have been some complaints, satisfactorily resolved. There also have been a few minor product liability actions, and limited product recalls. Company X is making a reasonable profit.

Enter the Medical Device Good Manufacturing Practices (GMP). Company X organizes to comply. After listening to a number of experts on the ways of compliance, they develop a comprehensive GMP compliance system.

Not unexpectedly, costs increase and profits decrease. However, unexpectedly, customer complaints also increase! Then, liability actions increase and insurance costs rise. FDA inspectors find non-compliance!

Company X adds resources to cope with the myriad of problems. Costs increase further--profits decrease even more. The spiral continues. The business fails.

WHY?

The answer is simple. Company X did not attend to their own business FIRST. They directed their resources toward GMP compliance, but lost the business.

THE STATE OF MEDICAL DEVICE BUSINESSES AND GMP'S

Most medical devices from most manufacturers ARE safe, effective and meet the customers' needs. A little reflection will demonstrate the verity of this statement. Examine first the medical devices you know best--your own. The statement certainly applies. You may have a few problem devices, but you are working to solve those problems. Look now at the medical devices you know next best--your competitors'. You will find that the same situation holds true; and for a very good reason. Both you and your competitors are in business to earn a profit for the business owners--the stockholders. If most of your products were not safe and effective, and did not meet your customers' needs, your business would not long survive.

Since most medical devices from most manufacturers are safe and effective, and meet the customers' needs, it follows that most manufacturers are already following good manufacturing practices. They are doing many things right! You are doing many things right! To be sure, many of your good practices may be an unstructured and undocumented way that you do business; however, these good manufacturing practices do exist. They are responsible in no small measure for the success of your business.

When some businessmen examined the FDA proposed GMP's for medical devices, they stated they should be called "good business practices" instead of "good manufacturing practices" since the scope of the proposal extends far beyond fabricating a medical device. Design,

production control, maintenance, industrial relations, quality control, packaging, and distribution are some of the other traditional business functions affected. Make no mistake, GMP's are quality control system requirements. They are the requirements for that business system which controls the quality of medical devices. GMP's are not, however, necessarily synonymous with quality control organization. While there are organizational aspects to the GMP, the scope of the requirements includes far more than that usually within the purview of the traditional quality control organization

A BUSINESS DEFINITION OF "QUALITY"

Before one can address the subject of a business systems approach to GMP's, a full understanding of the meaning of the term "quality" in a business sense is essential. Almost every text on the subject of quality control includes (usually in Chapter 1) a definition of "quality". Appropriate as these definitions may be, they are from a professional technology rather than a business point-of-view. They suffer from the "zero defects" or perfection syndrome. While there may be aspects of the business where striving for perfection is productive and profitable; there are many other areas where the converse is true.

QUALITY IS THE DEGREE TO WHICH THE ACTUAL MEETS THE EXPECTED. This is a business definition of "quality". Note that this definition is sufficiently broad to include every aspect of the business. Note also that "quality" can be both negative or positive in degree.

When the actual is less than the expected, the quality is too low.

When the actual equals the expected, the quality is optimum.

When the actual exceeds the expected, the quality is too high.

For example, suppose that a device performance will meet the customer's expectations if a certain component tolerance is met. Suppose further that an over-zealous design engineer puts only half this tolerance on the drawing for a margin of safety. Already, the actual (engineering drawing) exceeds the expected (customer requirement) and the quality is too high. In one case, a production worker, equating a tight tolerance for a need for perfection, takes extra time and effort and uses only a portion of the allowed tolerance. Again, the actual (component) exceeds the expected (tolerance) and the quality is too high. In another case, a production worker may believe that the tolerance is unrealistic, and produces components that are out-of-tolerance and are rejected by the inspector. In this case the actual (component) is less than the expected (tolerance) and the quality is too low.

Consider the excess costs--and the profit loss--in these examples. The situation would be even worse if the rejected components (actual) did in fact meet the customer's requirement (expected). It is for this very reason that it is important from a business viewpoint to define quality in a manner which permits control against being too low or too high. The general relationship between the actual, the expected and the relative business risk is depicted in Fig. 1.

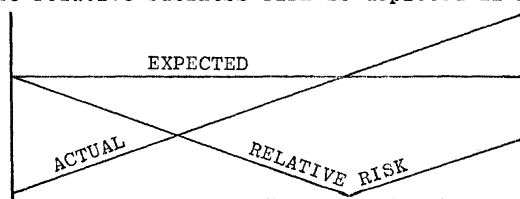


FIGURE 1

Note that when the actual is well below the expected, the relative business risk is quite high. This is the classic case of too low quality. However, the relative business risk increases when the actual exceeds the expected and the quality is too high. The relative business risk is a minimum when the actual equals the expected.

The entire process of business management (and medical device businesses are no exception) involves determining the expected and controlling the actual to meet the expected. This is the substance of the business systems approach to GMP's. It is based on this author's fundamental belief that if you operate your business in such a way as to maximize long term profits, you will produce medical devices which will be safe and effective, meet your customers' needs, meet the regulatory requirements and minimize product liability.

THE BUSINESS SYSTEMS APPROACH TO GMP'S--A 10 STEP PROGRAM

You best know your own business--its personality, its resources, its constraints. You know your business better than your customers know it, better than other outsiders know it, and better than FDA inspectors know it. Your GMP must be specifically tailored to your business, and it will be for your business only. It would be utter business folly for you to attempt to overlay someone else's GMP onto your business system.

The following 10 steps are designed to assist you in discovering your own good manufacturing practices, and to enable you to develop your own GMP compliance system at a minimum cost. During the process you may find that you need to alter your business system to meet your own business needs. Once this is accomplished you will very likely find that you then meet the GMP requirements.

STEP 1--Determine your present business system.

Your present business system consists of defining the expected and controlling the actuals to meet the expected at many levels. How do you determine customer expectations? Do you exercise any control over these expectations? How do you translate customer expectations into engineering requirements? What are the controls on design? How do you translate design requirements into work orders, tooling, purchases, inspection and labeling? What are the controls? How do you establish the expectations for facilities, capital equipment, expense tooling and gaging, personnel selection, personnel training, and facility equipment maintenance? What are the controls?

To assist you in the task of determining your present business system, the author has available on request a "Checklist of Business Systems for the Control of Quality". This checklist consists of more than one hundred questions to determine those business systems which you may have or need. All of the questions may not apply to your specific business. However, many of the questions will prompt additional questions which will emerge from your intimate knowledge of your business.

STEP 2--Diagram your present business system.

Once you have determined your business system, diagram it. You can use the full range of symbols which the systems engineers are fond of using; however, in most cases, a simple block flow diagram will suffice. There are several reasons for diagraming your systems. It will:

1. Help you to understand your system.
2. Help others to understand the system.
3. Facilitate the detection of redundancies and gaps.

4. Provide a reference baseline for your system audits.
5. Provide a reference baseline for system changes when products, resources and constraints change.
6. Simplify the drafting of operating procedures which will be your GMP "manual".

STEP 3--Document business system requirements (policies) to meet your business needs.

Examine your business system diagrams. Ask the question, does the business system meet my business requirements? To answer this question requires that your business requirements be known. These requirements should be documented and will form the policy statements for your business. Such policy statements are important to business management for they define requirements--what must be done--rather than the detailed procedures--how it is to be done. The policies you establish will include most, if not all the GMP requirements. Policies tend to be static, changing only when the fundamental business changes. Policies are especially important for multi-plant operations. The operating procedures at each plant may vary according to facilities and other resources, and constraints. However, each plant can meet a common policy with differing procedures.

STEP 4--Evaluate and modify your system to meet your business policy.

During Step 3 you may have found that your business system has excesses or deficiencies with respect to your business requirements--your business policies. Adjust your business system so that it meets your own business policies. You will find that your business system diagram will facilitate changes in a manner avoiding redundancies and gaps, and providing the links to other business systems.

STEP 5--Adjust the business system to GMP requirements.

Only after you have a business system design which meets your own business needs should you look to the GMP. If you have completed the previous four steps satisfactorily, you will probably have either no adjustment or only a minor adjustment to the business system to meet the GMP!

STEP 6--Document your business system technique (procedures).

Your operating procedures must be documented so that those who are responsible for that portion of the business can perform the tasks consistently and in a manner which you have determined to be most effective and efficient. These operating procedures will become your own GMP compliance manual. It, along with your policies, is the primary document against which an FDA inspector will audit your business for GMP compliance. The procedure writing task is almost routine when it is done from the previously diagramed business system. Include the flow diagram as a part of the procedure.

STEP 7--Design forms for information retrieval.

Business systems seem to require considerable paperwork. Many forms are designed to collect information. Both blank and completed sample forms should be included in the appropriate procedures to assure proper completion and use. Design your forms for the efficient and accu-

rate retrieval of information. By using this approach you will tend to assure that useless and costly information is not collected. Forms designed for information retrieval are also usually forms in which it is easier to record accurate and legible information. Of course, if there is a conflict between ease of information entry and ease of information retrieval, suitable trade-offs predicated upon business risks should be made.

STEP 8--Collect data for use, not storage.

Businesses collect vast amounts of quantitative data, much of which ends up in filing cabinets or computer files and is never analyzed for any useful business purpose. The storage costs of such data is staggering. Before you require the collection of data, make sure that you have a specific business purpose for that data. The analytic techniques or other business purposes should be defined in the procedure. Data which is "nice to have" or duplicate data is seldom justifiable or profitable.

STEP 9--Test and adjust the business system.

Even if you have made only minor modifications to your present business system, it is good business practice to try it out on a limited basis before a full-scale implementation. A limited trial will often reveal errors and inconsistencies which are easily rectified at that stage. This is especially true of information and data collection forms. It is usually much more costly to alter a system which has been fully applied. Be sure to include any adjustments you may make as a result of the trial application in your business system diagram.

STEP 10--Audit and adjust the business system.

Business systems are dynamic. They change with new or different people among other factors. Subtle changes can occur in practice which either improve or degrade the system. It is good business practice to periodically audit the business system to assure that it is continuing to function as designed. Adjust the business system, diagram, procedure, and forms as necessary to meet the business policies in an effective and efficient manner.

SUMMARY

The FDA medical device good manufacturing practice regulations do not, in general, require more of your business than you should already be doing in order to maximize your long term profit. In most cases, what you do for your own business will satisfy the GMP requirements.

Start with what you have. Change what you have to meet your own business needs. Adjust your business systems, if necessary, to meet the GMP. Document your business system requirements in policies, and your business system techniques in procedures.

The result will be a business system which meets your own business needs first; and will also conform to GMP requirements.

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PRODUCT LIABILITY IN EASTERN EUROPE

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INTRODUCTION

To correctly understand the status of Product Liability (PL) in Eastern Europe it is first necessary to understand some economic and legal aspects of the Socialist countries of Eastern Europe. Then the status of PL will be presented on a domestic level and separately on an international level.

This paper does not attempt to pass on the effectiveness or quality of the systems, methods, and approaches described as operating in the Socialist Eastern European Countries. The presentation will be of facts and information as known to the author.

Ownership of Business and Industry

Industry and business is organized into enterprises, corporations and companies as in the U.S.A. These enterprises are then grouped into industries which are then grouped under ministries. Ownership is in the hands of "the people". Gross profits are distributed to such areas as capitalization, expansion, and new product lines, while the net profits (dividends) go to the general revenues for use in the economy.

Manufacturing companies, research and development institutes, medical facilities, and insurance companies are all so state-owned.

Citizen Benefits

As is common with Socialist countries, the population is provided with an extensive social program. This program includes medical, dental, surgical, and hospitalization coverages. A form of what would be called Workman's Compensation is also available, along with coverage of lost wages for a great variety of reasons. These Eastern European Socialist countries also have a "full employment policy". Able workers are to be employed, or they can be charged with being "parasites" and, thus, subject to arrest. Therefore, the worker has to be offered a job where he can earn a living.

Legal Environment

The Eastern European nations (EEN) have various laws relating to industrial safety. These laws usually cover workplace safety, with some laws also dealing with the environment, both inside the enterprise and in the general outdoors. Federal Quality Control laws also exist. For example, Czechoslovakia (CSSR) has had a State Quality Control Act for at least ten years, and they are currently in the process of revising and updating this act. One of the expected results will be a model total Q.C. system.

The USSR has been engaged in activities aimed at improving their legal assurance of product quality for the last ten years, and also expects to have a federal model for technical control departments in industrial enterprises, a model for quality inspectorates in industrial ministries, and for testing centers. This work is currently going on, headed by the State Committee for Standards of the USSR Council of Ministers.

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The Socialist bloc also uses the technique of arbitration rather than going to the courts as is done in the U.S.A. to settle questions of warranty, poor quality, poor reliability, and other breeches of contract.

Standards in the EEN have the weight of law, being mandatory. Non-conformance to standards is prosecutable, resulting in material (economic), disciplinary and/or criminal actions against those responsible. At the present, the EEN are working on standardizing-harmonizing-standards between them.

Standards are called out in contracts, or if not, the applicable standards pertaining to the product or service are in-force. A contract cannot be made for a quality level lower than the one specified in a state standard, unless the appropriate standard setting body gives prior approval, and an appropriate price reduction is made. When standards are violated, there are a specific set of rules governing applicable penalties for enterprises, management personnel, and workers. Criminal charges may be brought in cases of repeated and flagrant production and shipment of product that creates a danger to the consumer's health and safety, brings about losses for the enterprise, and/or losses for the economy as a whole.

Product liability insurance as it is known in the U.S.A. is not offered to enterprises by insurance companies in the EEN, although liability insurance as a form is known and used, e.g., automobile liability insurance is required in EEN.

The EEN also regulate the quality levels of their imports and exports. State inspectorates grade domestic product into classifications that permit some to be sold in domestic or international markets, e.g., Grades I and II; some to be sold only in domestic markets, e.g., Grade III; and some to be sold only domestically, at discounts, as other than first-class product, e.g., product not meeting at least Grade III.

Imported product is also inspected and tested for conformance to quality levels spelled out in contracts. In this activity, quality marks may be used to mitigate the need for such inspections and tests.

THE STATUS OF P.L. ON THE DOMESTIC SCENE

Complaints about poor quality have been on the increase in the EEN. The greatest percentage of the increase has come from industrial consumers that are demanding stricter adherence to standards, and an increase in the quality levels spelled out in these standards.

Product Liability in the U.S.A. means liability by the manufacturer and other members in the distribution chain, for damages and injuries incurred by consumers and innocent third parties, when a product fails. The EEN do not have this concept of P.L. Their definition of P.L. is that of legal responsibility for poor quality in general - responsibility for product that does not conform to standards.

Because of the social and legal conditions spelled out earlier in the paper, P.L. will - cannot - become the problem that it is in the U.S.A. In the case where a consumer is injured by a product, their social programs cover the costs of hospitalization, medical costs, and lost wages. As with most of Europe, and countries other than the U.S.A., suit for "pain and suffering" is not very common. The legal doctrine of strict liability in tort is not used, with reliance for assigning liability being on negligence and breach of warranty.

The decision on where liability exists is made on (a) does the product conform to the standard, and/or (b) has the quality level that was warranted been violated. If liability is established, the fines are assessed as mentioned above, or in the case of an industrial consumer, the fine is determined by the process of arbitration.

Product Safety, as distinct from P.L., is receiving more attention in the EEN. As mentioned earlier, there are laws pertaining to the safety of products - safety being one of the quality characteristics of product. Several EEN were represented at the First European Seminar on P.L. hosted by the EOQC and the Italian Association for Quality Control, in Venice on 28-29 April 1977. As a

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matter of fact, the delegate from the USSR, who presented one of the papers at the conference, expressed an interest in having the next conference in his country. The month following the Venice seminar, the first P.L. conference to be held in the EEN, took place in Prague, CSSR under the auspices of the National Committees for Quality and Reliability, of the Czechoslovak Scientific and Technical Society.

They have recognized that the same techniques that have been used to attain high quality and reliability levels can also be used to attain high safety levels, e.g., Design Review, FTA, FMEA, Data Collection and Retention.

THE STATUS OF P.L. ON THE INTERNATIONAL SCENE

On the international level, the P.L. situation begins to bear a greater resemblance to that found in Western Europe, Japan, and the U.S.A. This is because as the products of the EEN move into international markets, they are subject to the laws and conditions found in these markets. Product safety regulations and standards - whether voluntary or mandatory - have to be met. Industrial safety - OSHA type-laws also have to be contended with.

The author's experience has been that product from the EEN has as far back as three - four years ago, been involved in P.L. litigation in the U.S.A., and Eastern European companies in some cases have been unable to ship their product to the West because of the inability to get P.L. insurance - a prerequisite to entering the market.

As laws and legal theories change in the West, the EEN will have to not only be aware of them but conform to them. Therefore, as their products for international trade will be changed to meet changing standards relating to product safety, their domestically consumed product will also reflect these changes. It would be uneconomical and inefficient to carry on a two-tiered product line.

CONCLUSIONS

Domestically, the emphasis in the EEN is developing in what in the U.S.A. would be called Product Safety rather than P.L. However, on the international level, some of the P.L. problems that have been experienced in the U.S.A. are making their way over there.

Their concept of P.L. is being developed within the efforts on legal problems of product quality control. To them, P. L. means responsibility for poor quality in general, not responsibility for damage to property and injury to person that arises from product failures. Their criterion of poor quality is basically that it did not conform to the mandatory standard.

Adherence to standard, misuse or misapplication of product, and adherence to warranty terms are all acceptable defenses against claims of poor quality.

Where liability for poor quality is established, fines are assessed according to pre-determined formulae spelled out in the laws, or determined through arbitration. This procedure applies to cases where poor quality causes bodily injury, property damage, and economic loss. As for the injured person(s), the social programs compensate them according to state law, and legal action is not resorted to.

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CONTRIBUTION OF QC TO PRODUCT LIABILITY AVERSION

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INTRODUCTION

Fellow quality professionals, many speakers at meetings like this, start their presentations with a joke or two - Today I am not going to do that because I consider the current product liability situation facing American industry to be a very serious matter.

This afternoon I plan to review some of the basic issues in product liability today and review some statistics from the most current source material. I will attempt to indicate to you the seriousness of the problem and it's possible impacts on industry in the U.S. and then outline for you some techniques which can assist you in developing quality control oriented strategies to avert or at least minimize product liability risks in your companies.

First, let's review some basic definitions to insure that we are all hearing and understanding the same thing.

Please bear with me if these definitions are second nature to you, perhaps some of us are new to these ideas.

What is product liability?

There are many differing ideas on this subject which we hear so often BUT, basically, product liability is the simple concept that a provider of goods or services has an obligation to the recipient or consumer to insure that the consumer is not injured by their product and that if there is an injury, the injured person will receive some compensation.

Many people consider non-injury situations such as warranty claims, and other related problems to be a product liability issue but a warranty claim is really a problem of contract compliance to be precise and I do not intend to discuss this issue today.

Why do we seem to have so many problems today?

Fundamentally, because of changes in society which are reflected in judicial actions and in legislation.

How many of us have heard the expression "caveat emptor" or "let the buyer beware"?

Not too long ago, the phrase seemed to govern many product/consumer relations.

In the last 6 - 10 years our society and for that matter much of the world's society have repudiated that concept and today's product users have increased their expectations as to what they will receive when they purchase an item or service so that now the slogan might be better stated "caveat vendor".

Why has this occurred?

Well, a lot of people mutter labels such as "Ralph Nader", liberals, and other less complimentary phrases but suffice it to say that there are probably many causes which could be talked about all afternoon, let's just say that it has happened!

Is there a crisis today?

Well, President Ford established a project in mid - 1976 called the Interagency Task Force on Product Liability - pulling together many Federal agencies which has generated as Gov't bodies seem to do, a lot of reports. At the briefing meeting held at the Dept. of Commerce, in January 1977, chaired by the then Under Secretary of Commerce, Mr. Vetter, the conclusion was presented that NO crises existed in general in U.S. industry, though there were some problems. (1)

Now, admittedly, from the Washington viewpoint looking at many thousands of companies across the country there may not be a crisis but if you are a small manufacturer who suddenly can't obtain product liability insurance at any price you might have a different viewpoint.

Nevertheless, some facts have been published which partially indicate the magnitude of the product liability problem today.

A review of a number of trade association surveys of product liability experience has indicated that substantial increases in product liability insurance premiums have been experienced in the 1970's.

As depicted in fig. 1, in the period 1969 - 1974 average product liability insurance premium increase for manufacturers was 154% while in the period 1974 - 1976 the average increase was 320%. (2)

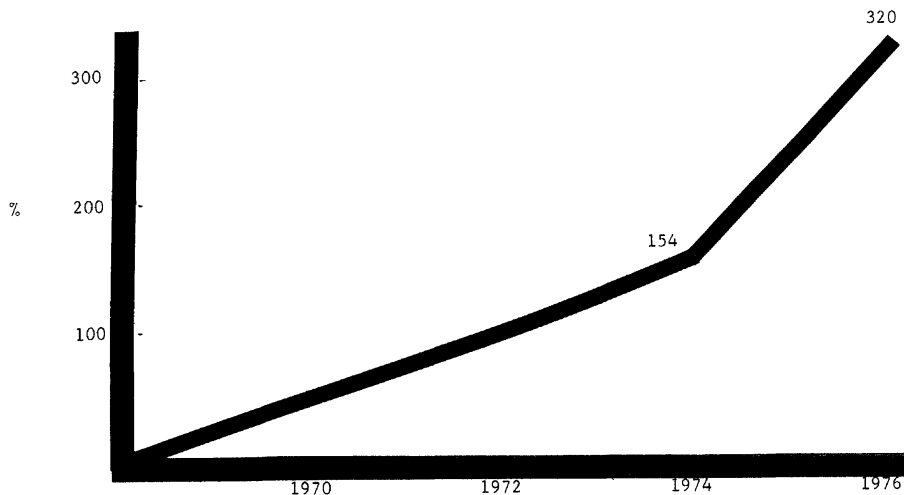


Fig. 1 Increase in product liability premium costs

Many of these companies reporting premium increases had never experienced a single product liability claim and some were companies with a long tradition of safe, quality products.

I am sure that we have all read of spectacular jumps in premium reimbursement of 400% to as much as 1900% but this slide reflects data from the Task Force Industry Report and AMLA reports.

Due to the high costs of insurance and also due to non-availability of insurance to some firms, many people are forced to operate w/o insurance, as shown in Fig. 2, a substantial number of small manufacturers operate in this manner. (3)

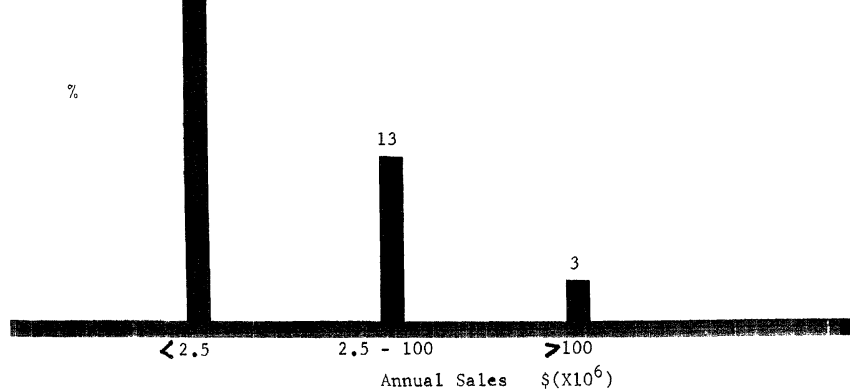


Fig. 2 U.S. Manufacturers without Product Liability Insurance - 1976

The average amount of damages per firm in the survey claimed in new law suits rose from \$476K in 1971 to \$1.7 million in 1976. (4)

Certainly, these numbers should make us all stop to think.

Another significant statistic to consider is designed to make those of you sitting thinking, "I'm involved in industrial products, thank God I don't have the problems of consumer products QC"!

Don't be too smug, you're not very safe - a recent insurance industry survey indicated that 71% of product liability claims over \$100,000 paid in 1975 by the surveyed companies involved industrial products, not consumer products with an average cost/claim of \$287,964. (5)

This seems to be counter to popular opinion, why?

The basic problem here is inadequacies, real or perceived in workman's compensation programs around the country. Don't forget, a worker accepting workmen's compensation treatments cannot sue his employer.

If the injured worker receives a settlement from his employer's workmen's compensation insurance carrier which doesn't meet his or her expectations, their only recourse is to sue the manufacturer of the machine involved in the injury and this clearly has significant effect.

An Example

What many of us in this room would like to consider as rational common sense rarely seems to apply in these cases. Recently a QC inspector was injured, losing a portion of his index finger when he attempted to un-jam a conveyor drive chain. Prior to the accident this individual had been warned several times, by his supervisor, to call maintenance if there was any problem and any moderately intelligent person could be considered to know enough to stop a machine before poking at a drive chain. These concepts should certainly have protected the conveyor manufacturer from a lawsuit. Oh, by the way, there are a couple of other interesting facts here, including the age of the conveyor, 23 years, the fact that it was in the hands of a 3rd owner and that when built 23 years back it had been driven by a well guarded V-belt not an unguarded chain drive!

Nevertheless the conveyor manufacturer still paid out \$44,000 to the injured operator.

Reasonable? Perhaps not, but it happened.

What can be done?

Now that I have set the scene, instead of attempting to resolve issues which will only be responsive to fundamental changes in society and the law, I think we should spend some time looking at what can be done to reduce the risks of product liability problems facing manufacturers today.

You may say at this point, it's a simple task, "all you have to do is make the products to the specifications" and you won't have any product liability problems!

Unfortunately, I'm afraid that won't work.

But fortunately, from a QC practitioner point of view, I think that the present product liability crisis situation represents a unique opportunity and challenge to QC people.

If the QC profession steps forward and responds in the appropriate manner, not only will the problems be reduced but the position and image of QC as a management group who are significant contributors to profits will be enhanced!

This challenge can be met successfully and simply by remembering the fundamental principle of Quality Assurance/Quality Control. That is, "to insure satisfaction of the customer's needs".

Now, of course, we may need to do a few things differently, or with a slightly different emphasis to be sure of maximizing the effectiveness of our product liability efforts but ultimately, fulfilling this credo will assist our mission immensely.

By the way, I consider those of us in the QC discipline to be among the most capable people in industry to accomplish this task because of our current responsibilities and activities in most of American industry.

Some of the following suggestions, by the way, are going to sound like "how to establish a good QC program" but after all, that is my theme so bear with me, and think as I talk how you could expand your existing programs to include product liability considerations.

To begin - first step, and a very important step, is the promulgation by top management of a clear and unequivocal policy which basically states that the company wants to provide it's customers with safe products.

As we all know from experience, without this kind of policy statement, and commitment and support, QC's efforts will be stymied to a great extent.

Next, we have to establish a mechanism to accomplish this policy; and since I'm addressing my remarks to QC people from large and small companies, please accept my statements as general recommendations which may be implemented with a slight modification or change in emphasis to an already existing QC system.

The most effective mechanism to implement this policy is a multi-disciplinary committee charged with product safety and liability exposure considerations.

My preferred organization concept for this Product Safety Advisory committee is as shown in Fig. 3.

This committee should exist at the top level of the organization and will basically establish detail policy and procedures for subordinate levels in the organization.

If you're a small company QC Chief this may be all the organization there is need for, if so action will be required as well as policy establishment.

For the larger firm, suitable committees of similar structures should be established down to the necessary levels in the firm usually where actual design or development activities are carried out.

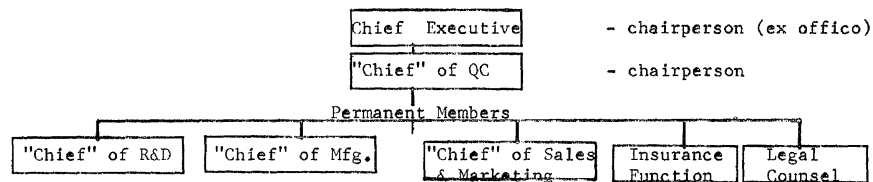


Fig. 3 Product Safety Advisory Committee

Regular meetings with carefully documented notes of actions, decisions, and recommendations should become an important part of the QC paperwork file at each committee level, with upward and downward communications mobility.

I think that having QC be in charge of this type of committee is a logical extension of the modern concepts of QC's role in industry reporting to top management for maximum organizational effectiveness.

What else should our basic policy state?

Additional elements of basic policy - Your firm's activities should include the incorporation of "state-of-the-art" safety engineering principles in all phases of design and manufacture.

Now, I'm assuming, that this is a new way of looking at an existing organizations' activities and methods. Any organization has at any one time both new products and existing products. It is one thing to set up a system to handle new products or, designs, but what about those products which have been around for awhile?

Actually, this can be handled quite simply:

Starting from establishment of your new policy, throughout R&D and product design and manufacture, state-of-the-art safety engineering principles will be incorporated in all new product development. In addition, an ongoing review of existing product designs will be established and maintained to provide for appropriate product modifications relevant to the current state-of-the-art.

Clearly, since no one has infinite resources to handle this review process, some system of prioritization is needed to decide which of the existing designs will be looked at first.

I would like to suggest that this prioritization be determined by assessment of the risk exposure of the various product's in your company's catalog and that this assessment should be a function of the Product Safety Advisory Committee. The amount and depth of design review for product safety considerations will vary enormously between different companies so I will offer some common, general principles -

1. Review the design according to generally accepted engineering/scientific principles from a safety consideration
2. Review your product's design against standards applicable in the industry
3. Review your product's design in comparison with competitive products
4. Possible risk exposure inherent in product
5. Risk potential from product misuse
6. Document all decisions carefully and completely

Make sure that all new product designs are tested to validate the design safety and quality objectives and that existing products have adequate records of product qualification.

Insure that adequate QC of all aspects of product manufacture is in existence to insure the ongoing accomplishment of the design safety and quality objectives.

Insure that adequate records of operations, inspections and tests are available to document the accomplishment of the ongoing QC effort even in a courtroom.

Insure that all operating instructions, product labels, product bulletins, catalogs and advertising consider the user's safety and the producer's exposure to product liability risk.

Plan for the worst

There is another facet of my program which must be looked at now which may never be needed but certainly must be part of your planning.

What do you do when all the actions listed earlier have been done and you still get a letter from a lawyer, or you become aware of an "incident" involving one of your products?

Depending on the complexity of your organization and the degree of risk exposure that your products bear, your response may vary. But the need for a planned response pattern is definite.

Basically, each company should have a system designed to obtain all pertinent facts concerning any incident which causes injury, death, or damage to property. Obtaining possession of the product involved in an incident is highly desirable also but if this happens a system of careful control of the evidence must be maintained to make sure that the information is of use in court defense.

All of this information must be communicated rapidly and completely to legal and insurance functions and this can be most effectively handled through the committee structure though the timeliness of the system must be kept in mind.

For those of you interested in the detail of "what to do after the incident", I would recommend your obtaining a copy of the excellent paper presented at the PLP77E by Mr. James Gardner. (6)

Conclusion

In conclusion, I would like to state firmly that the situation in this country concerning product liability exposure is going to get worse before it gets better at least from a manufacturer's viewpoint and that the "getting better" will quite likely be years from now.

The argument that, ultimately, society will be served through the exercise of the free market system is only applicable in the long term and unfortunately most of us have to operate on a day to day basis in our jobs.

To insure the short and long term capability of your company to withstand the problems of product liability risks and attendant insurance problems and costs a system and plan are needed.

I maintain that such a system, following the outline I have presented, can best be developed by an aggressive and capable QC group since these concepts are extensions of well accepted QC principles.

Ultimately, a well run Product Liability Risk Aversion program will have a positive effect on profits and, after all, that is the goal of all management activities.

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SAFETY AND RELIABILITY ANALYSIS USING FAULT TREE

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INTRODUCTION

There have been a significant number of words written about safety, reliability and fault tree analysis. After many of those references have been read and studied, the thought occurs that perhaps another set of words, organized though they may be, is not needed. Yet, the human inclination to restructure the previous work of others, with the hope that a small contribution can be made in the process, is difficult to subdue.

This paper will define, compare, and discuss safety and reliability. It will also present the rudiments of fault tree analysis, which can be used to analyze the safety and/or reliability of a device, product, system, process, or service; usually "product" will hereafter be used to mean any or all of these terms.

SAFETY - RELIABILITY

It is generally agreed that a safe product is not necessarily a reliable product; the converse is also true. The significance of that statement, however, is not always so generally appreciated by managers, designers, and others who are responsible for the products appearing in the marketplace. The well meaning people that put out a commercial paper cutter that "reliably" cuts arms as well as paper did not appreciate that fact, nor did the people who shipped some very safe electrical appliances, without cords. The latter problem is merely a nuisance; the former is deadly.

There are many situations in which reliability does imply safety, at least to some degree. If the light screen enclosing a press reliably detects an object which intersects it, at least one element of the system is contributing to the safety of the press. Note that it has not been said that in this case reliability is synonymous with safety; it only assured that one part of the press control operated in a safe mode.

Graphically, the partial intersection of reliability and safety can be illustrated by a Venn diagram of Figure 1.

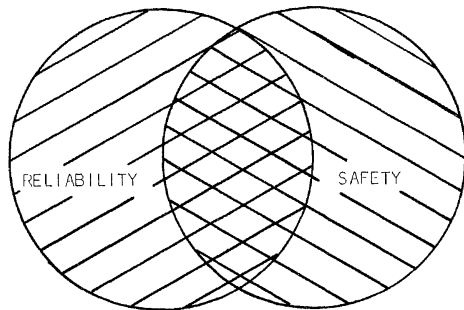


FIGURE 1 INTERSECTION OF RELIABILITY AND SAFETY

The double cross-hatched area represents those situations where the reliable functioning of a product also implies a safe mode of operation. Of course, it is never possible to obtain total intersection of the two domains for several reasons:

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all hazards can never be known; the domains will probably not be the same size; the time and funds are not available to do so.

Before continuing, it would be well to define a few concepts and terms. Human safety seems to be the dominant interest and concern of most people, although equipment and economic safety should not be forgotten. It is product liability litigation, with its consequent economic implications, which has placed the safety of people in the foremost position. Government agencies such as the Consumer Product Safety Commission, have also accentuated personnel safety above all others. It is reasonable that the discussion of safety primarily concerns the well being of people. That which is said about the safety of people would generally apply to the safety of equipment.

Safety is defined as a judgement of the acceptability of risk. Risk is a measure of the probability and severity of harm. It can quite succinctly be said, then, that "A thing is safe if its risks are judged to be acceptable." [1] All that is succinct is not simple, alas. The risk must be measured. This can be accomplished, but it requires the accumulation of data, and is probabilistic in nature. The measurement of risk is objective. The second ingredient of safety, judging the risk acceptability, is quite subjective, however. The judgement or evaluation process is a function of personal and cultural background, technical sophistication, familiarity, prior exposure and many other human ingredients. Lowrance [1] devotes a chapter to each of these two facets of safety. For additional background on risk perception, the reader should examine several works by Chauncey Starr [2], [3].

Reliability is defined in terms of operating function, time and environment. Among the many similar definitions available, NASA defines reliability as "the probability of a device performing adequately for the period of time intended under the operating conditions encountered." The reliability of an operating product can be objectively measured with data accumulated over the operating period. However, prediction of the reliability of an identical or similar product is a subjective concept. This is a subjective step because of the belief that the data from the operating product applies to the similar product. Thus, although reliability can be objectively measured, it is probabilistic in nature, and its application for prediction is a somewhat subjective operation.

The probabilistic nature of both reliability and risk makes it impossible to predict the outcome of any discrete event. Only the average outcome of many events can be predicted. Even this is predicated on the subjective notion that the average (probable) outcome of a set of previous events is representative of a set of future events. Safety, in fact, has two subjective aspects to it, i.e., that which is associated with risk as above, and that due to the judgement of the acceptability of the risk.

Because of the probabilistic nature of reliability and safety, it is important to optimize their probabilities, consistent with reasonable cost-benefit decisions. It is vital to know, as well as practicable, the values of the various event probabilities and the nature of the sensitive segments of the product; fault tree analysis does this well.

FAULT TREE ANALYSIS

A fault tree is a graphical record of an analyst's logical and systematic answers to the question, "In what ways could a given undesired event happen?" It is a systematic, deductive analytical method to identify those combinations of events which will result in the undesired top event. For example, an undesired top event might be "Overhead Projector Fails to Light." With the top event defined, the formalized process using event symbols and logic gates to link basic events to the top event can begin. Among the requirements for a successful fault tree are a thorough knowledge of the product, a logical thought process and a bit of creative foresight.

After a fault tree has been structured, it can be evaluated either qualitatively or quantitatively or both. The end product of the effort should be a listing of the critical paths which lead from basic events to the top event. This identifies the minimal sets of components that can cause failure of the product (top event) if the components fail. A qualitative analysis determines the critical path, or min cuts.

A quantitative analysis requires data in the form of probabilities. Although component failure rate data is available, it is not likely to be readily available in

most useful form for all components of interest. Some may have to be developed; some may have to be "adapted" from related component data. The most difficult "component" to quantify in probabilistic terms is human behavior; it is most likely to introduce error in any quantitative analysis. Because of these difficulties, there are those who take a dim view of the value of a quantitative analysis based on such "questionable" data. They refer to such efforts as worship of numerology. There are others, however, who would prefer to have the quantitative analysis based on the best available data while taking a realistic view of the probable error it contains. They feel that it is better to have numerical results of possible substantial error, and use them carefully, than to have no quantitative results at all.

The request was that this paper should explain the construction and use of fault trees in safety and reliability analyses. Consequently, the reader who is well acquainted with fault trees will find little that is novel. The reader who knows what a digraph is, should go on to the next paper. For the rest who are not well acquainted with tree structures, there may be something to be learned. For those who wish to study the subject beyond this paper, Brandell [4] offers a short, easily read treatment. Another fine introduction appears in an American Gas Association publication [5]. Buys has written a generalized guide for structuring trees [6]. Two, among many, works by Lambert [7], [8] provide an excellent and comprehensive treatment; they are particularly recommended. A SIAM conference proceedings [9] contains a large number of more sophisticated, mathematically oriented papers. Brown's book [10] demonstrates the use of fault tree analysis for cost-benefit analysis. Lapp and Powers [11] present an algorithm for the synthesis of fault trees. The above suggested references are not exhaustive by any means, but will lead the reader to most of the significant literature on fault trees.

EVENT SYMBOLS

An "event" is the change of a component condition from one state to another. If the change of state occurs according to specification, the event is said to be normal. If the change is to an undesired state, or if the state of the component does not change when it should, the event is said to be abnormal; it is a fault event. It should be noted that every component failure is not a fault event. A fault is a component state that may somehow lead to the undesired (top) event. A component failure that does not enable the undesired event to occur is not a fault.

The basic event symbols which depict normal and fault events include the rectangle, circle, diamond, house, oval and triangles, as shown in Figure 2.

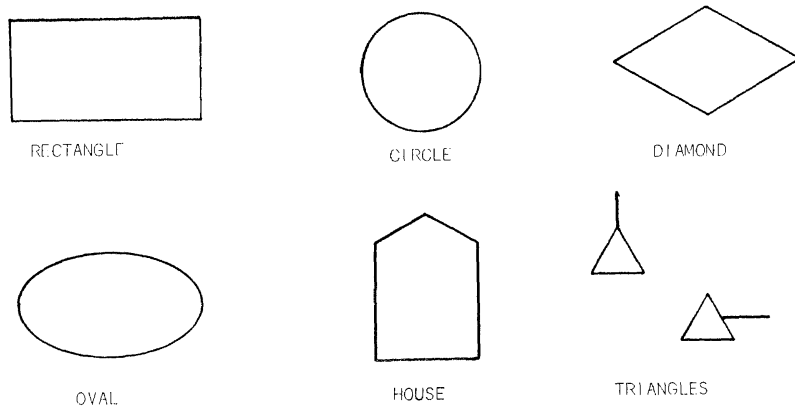


FIGURE 2 EVENT SYMBOLS

The rectangle event is called a gate event because it is the output of a logic gate. It depends on the contributory events acting through the logic gate, and on the type of logic gate to which it is connected.

The circle event is a basic event that requires no further development. It is always an input to a logic gate, depending on no other event. It is a characteristic failure of a product when used within its design envelope. It is considered a primary failure (primal). It is the result of a random failure.

The diamond event is one which is not further developed because it is not significant, there is not enough data, time or money, or when further development would duplicate information already known. It is considered a basic event.

The oval defines a conditional input to an inhibit gate. It specifies a condition that must exist to enable an input fault to cause an output from the gate. The condition may be normal or may be a failure mode.

A house event is one that is normal for the product and is expected to occur. It is not a fault or failure, per se.

The triangles are transfer symbols. Each pair will have a unique alpha-numeric symbol. The triangle with the line at the side specifies that the entire segment of the tree below the point at which the line is attached will be transferred to another part of the tree. The triangle with the line at the apex identifies the point on the tree to which a segment will be transferred.

The statement, "Projector fails to light," is a rectangular event. It could be an output statement from a logic gate at any level in a fault tree. The event statement appears in the rectangle as in Figure 3. Note that it consists of a subject, verb and descriptor; see Figure 4.

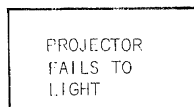


FIGURE 3: EXAMPLE OF RECTANGLE EVENT

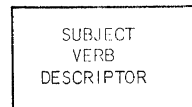


FIGURE 4: FORMAT FOR EVENT STATEMENT

In this case, the descriptor is the word "light." The mode of failure is clearly indicated. Similarly, the statement "Switch Fails Open" indicates that the state of the switch which may contribute to the occurrence of the top event is the open state. This format for event statements is especially important for quantitative analysis since the data for the probability that the "switch fails open" is different from that for the probability that the "switch fails" (in any mode). For consistent, logical structuring, the format of subject, verb, and descriptor should be used whether the fault tree will be used for qualitative or quantitative analysis.

LOGIC GATES

There are basically only two logic symbols or logic gates used in the construction of a fault tree, the AND gate and the OR gate. Sometimes the (•) and (+) mathematical symbols are added to the gates to emphasize which is which. The dot implies logical intersection in set theory; the plus sign denotes logical union. See Figure 5.

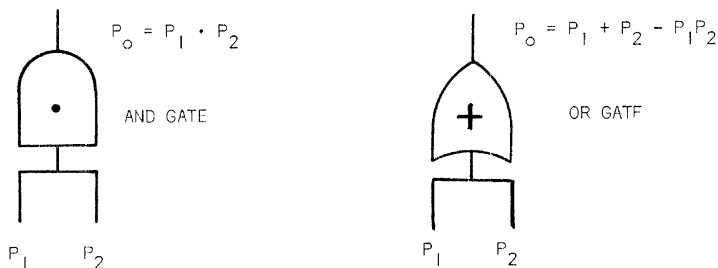


FIGURE 5 EXAMPLE OF AND and OR GATES

P_1 and P_2 are the probabilities that events 1 and 2, respectively, will occur. The logical output statements for the specific case of the two given inputs are shown.

In general, the output for an AND gate with N inputs is $\prod_{i=1}^N P_i(t)$, where $P_i(t)$ is the probability that the input event exists at time t ; this also assumes that the inputs are statistically independent.

The general relation for the output of an OR gate is $1 - \prod_{i=1}^N [1 - P_i(t)]$, the conditions on $P_i(t)$ being as stated for the AND gate. When $P_i(t) < 0.1$ for all i and t , then the OR gate output may simply be approximated by $\sum_{i=1}^N P_i(t)$.

Consider the example shown in Figure 6. The fact that the "lamp in socket is open" is caused by the failure of the first lamp and the defective spare lamp. In general, the output of an AND gate is directly caused by the inputs.

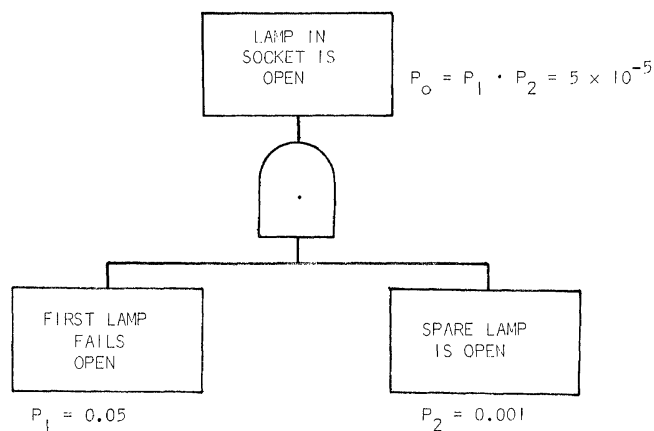
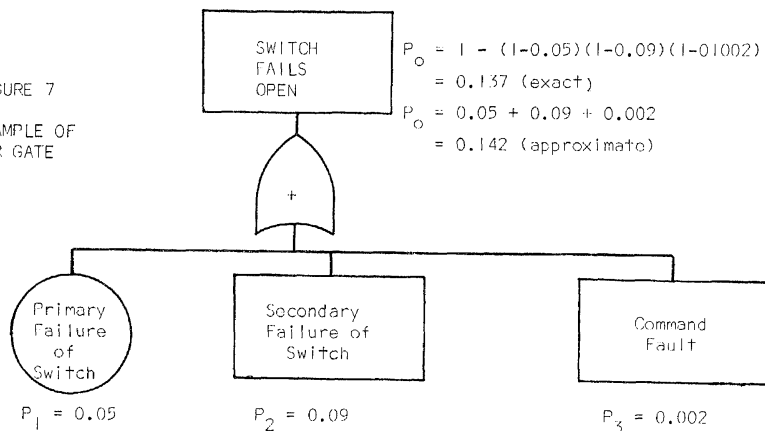


FIGURE 6 EXAMPLE OF AND GATE

The OR gate output is not caused by the inputs; the output is essentially just a restatement of each of the inputs. Figure 7 is an example of an OR gate. Note that the switch could "fail" open by wearing out (primary failure), being broken when dropped (secondary failure) or because it was opened at the wrong time (command fault). "Switch fails open" is a reiteration of each of the input statements.

FIGURE 7
EXAMPLE OF
OR GATE



AND and OR gates are the primary logic gates used in fault tree or other tree analyses. Any other logic gates are adaptations of the two basic gates. As an analyst becomes more sophisticated, he will use and "invent" a number of special gates. Among special logic gates are the inhibit gate, priority AND gate, exclusive OR gate, summation gate and other AND gates with unilateral or mutual dependence. Not all of the above will be discussed here.

The inhibit gate is a single input AND gate with an enabling condition which must exist for the possibility of an output to occur. The condition may be either normal or abnormal to the product. The probability of the output is $P(t) \times C$. $P(t)$ is the probability of the input; C is the probability that the conditional event occurs given that the input has occurred. An example of the inhibit gate is given in Figure 8.

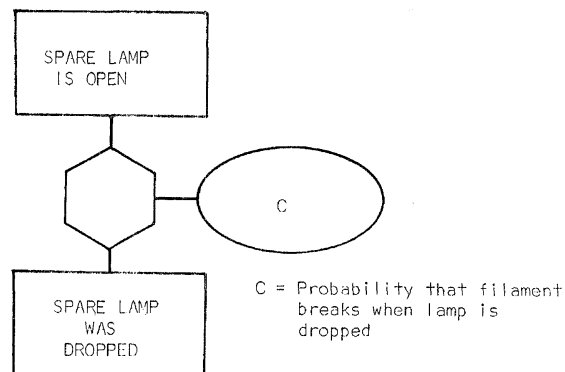


FIGURE 8 INHIBIT GATE EXAMPLE

The priority AND gate is an example of a gate for which the events have unilateral dependence. The input events must all occur and they must occur in a particular sequence in order for an output to occur. The unilateral dependence of a priority AND gate may be specified by a condition statement such as "event 1 before event 2," or by the format of Figure 9. This example implies that after the original lamp burns out an attempt is made to switch the spare lamp into the socket, but the mechanism fails. The first lamp must fail before the switch attempt is made.

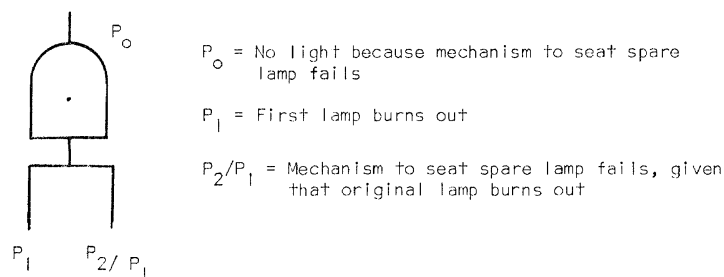


FIGURE 9 AND GATE WITH UNILATERAL DEPENDENCE

The exclusive OR gate will have an output if any one of the input events occurs, but will have no output if two or more input events occur. The summation gate requires that an acceptable combination of input events be present to produce an output. Inputs can be present in varying proportions although a minimum sum of inputs is necessary to obtain an output.

FAULT TREE CONSTRUCTION PROCESS

There is no mandatory or consensus standard method for going about the job of structuring a fault tree. However, Lambert [7] has suggested a rather well thought

out process; the nine rules are reproduced below:

Rule 1: State the fault event as a fault, including the description and timing of a fault condition at some particular time. Include (a) What the fault state of that system or component is; (b) When that system or component is in the fault state. Test the fault event by asking (c) Is it a fault?; (d) Is the what-and-when portion included in the fault statement?

Rule 2: There are two basic types of fault statements, state-of-system and state-of-component. To continue the tree (a) If the fault statement is a state-of-system statement, use Rule 3. (b) If the fault statement is a state-of-component statement, use Rule 4.

Rule 3: A state-of-system fault may use an AND, OR, or inhibit gate or no gate at all. To determine which gate to use, the faults must be the (a) Minimum necessary and sufficient fault events. (b) Immediate fault events. To continue, state the fault events input into the appropriate gate.

Rule 4: A state-of-component fault always uses an OR gate. To continue, look for the primary, secondary, and command failure fault events. Then state those fault events. (a) Primary failure is failure of that component within the design envelope or environment. (b) Secondary failures are failures of that component due to excessive environments exceeding the design environment. (c) Command faults are inadvertent operation of the component because of a failure of a control element.

Rule 5: No gate-to-gate relationships.

Rule 6: Expect no miracles; those things that would normally occur as the result of a fault will occur, and only those things. Also, normal system operation may be expected to occur when faults occur.

Rule 7: In an OR gate, the input does not cause output. If any input exists, the output exists. Fault events under the gate may be restatement of the output events.

Rule 8: An AND gate defines a causal relationship. If the input events coexist, the output is produced.

Rule 9: An inhibit gate describes a causal relationship between one fault and another, but the indicated condition must be present. The fault is the direct and sole cause of the output when that specified condition is present. Inhibit conditions may be faults or situations, which is why AND and inhibit gates differ.

An additional rule is to proceed in small steps; be verbose.

Basically the above procedure involves two questions: (1) Is the event a state-of-component or state-of-system fault? (2) What events are necessary and sufficient to result in the event in question (1)?

A state-of-component fault exists if failure of the component under investigation can itself be the fault. An OR gate is always used below a state-of-component fault event. The input events to the OR gate are the following three:

1. Primary failure - the component simply reaches the end of its life while being used within its design envelope.
2. Secondary failure - premature component failure occurs due to excess stress associated with its being used outside the design envelope.
3. Command fault - an unprogrammed operation of the component due to human or inanimate control mechanism failure, i.e., the right thing is done at the wrong time.

Figure 7 is an example of the format used for a state-of-component fault.

A state-of-system fault exists if a simple component failure cannot be the fault event. Below a state-of-system fault event an OR, AND, or inhibit gate may be used; occasionally no gate is necessary. The immediate minimum necessary and sufficient fault events for the state-of-system fault to occur will dictate which gate to use. Figure 6 is an example of a state-of-system fault, since the failure of the first lamp alone could not cause the output event. The spare lamp also had to be defective to cause the event "Lamp in socket is open."

To develop the fault tree beyond the secondary failure and command fault of the state-of-component fault, it is important to recognize their nature. Command faults are always state-of-system faults. The development of a secondary failure requires the use of an inhibit gate [7].

A secondary failure of a component results from excess operational or environmental stress. An operational stress would be an out-of-tolerance condition such as higher-than-specified current in a resistor. An environmental stress would be a detrimental energy input such as the heat resulting from the excess current in the resistor. Hammer [12] has a checklist of hazard sources. He also shows that the development of a secondary failure is detailed, requiring thorough product knowledge.

The operation of a switch at the wrong time is a command fault. The failure of the switch itself could not cause the fault. Hence, it is not a state-of-component fault; it is a state-of-system fault. To develop a command fault, the possible reasons for the fault must be found. For example, a malfunctioning transducer could signal a human or control mechanism to take unnecessary, improper emergency action.

AN EXAMPLE

Although the fault tree analyses of very complex problems have received widespread attention, the application of the method to relatively simple problems has merit because of the logical thought process and the graphical record which results. Examination of how a projector might fail during a lecture does not compare to a study of how safe a nuclear reactor is; however, such an exercise does give insight to the method.

A narrative of how a product operates should be written prior to actual fault tree construction. Because of space constraints here, that step will be omitted. Secondary failures are listed separately for possible further analysis. The sample fault tree shown in Figure 10 is limited by the space available in this paper; it could be further developed.

CONCLUSION

The concepts of safety and reliability have been defined and compared. It has been pointed out that the achievement of either can be improved by use of fault tree analysis. Some rudiments of fault tree analysis have been presented, with direction for significant sources of further information. An example fault tree for a simple event has been partially developed.

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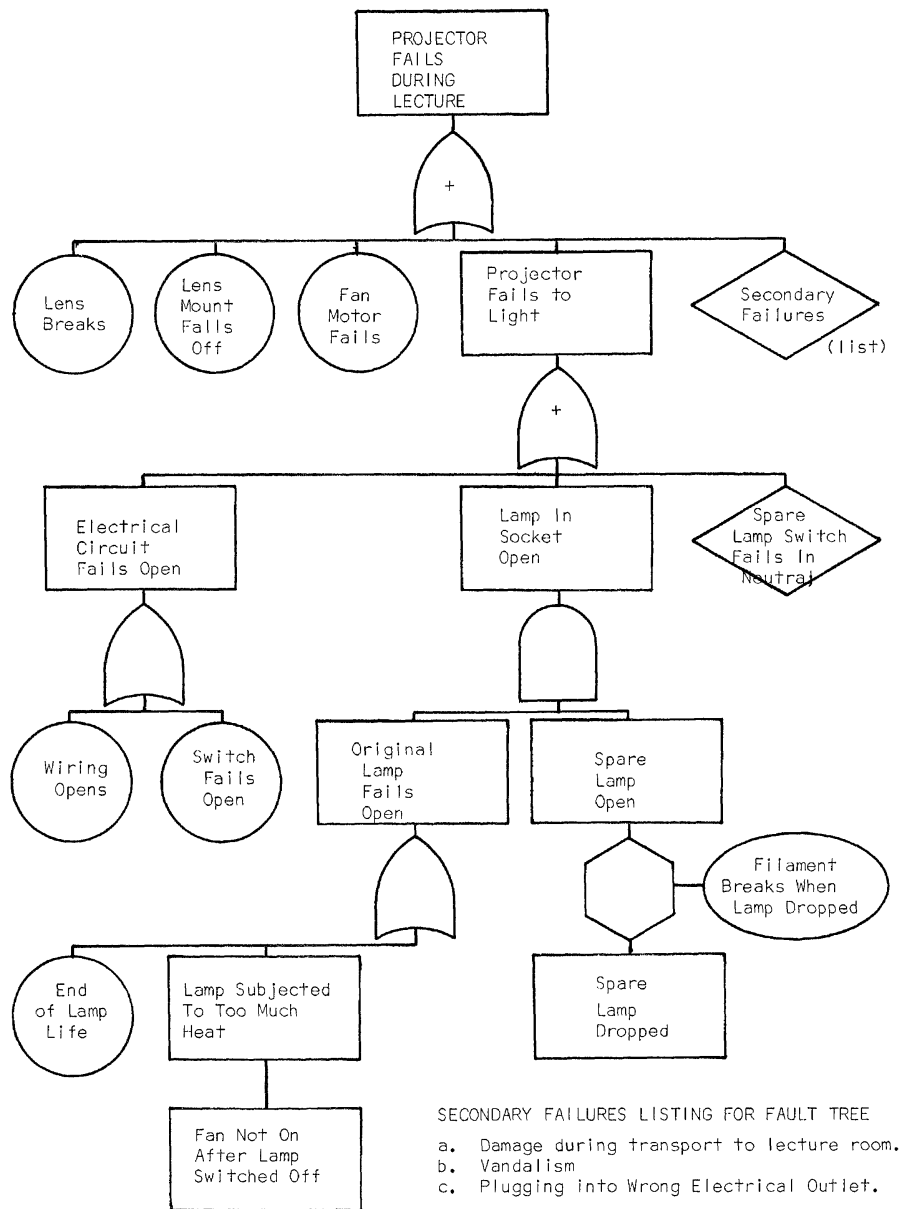


FIGURE 10 EXAMPLE OF PARTIALLY DEVELOPED FAULT TREE

STANDARDS AND SAMPLING PLANS FOR PRODUCT SAFETY

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Testing consumer products for safety raises many interesting and important issues in the areas of:

- 1) Human and engineering test methods,
- 2) Safety standards, and
- 3) Sampling plans used for testing conformance to standards.

This paper seeks to provide some perspective on consumer and industry viewpoints on product safety and the setting of safety standards. It then goes on to review sampling methods which appear useful in testing conformance to safety standards.

DISCUSSION OF CONSUMER AND INDUSTRY VIEWPOINTS ON PRODUCT SAFETY

At first sight, it would seem that the consumer at large has two somewhat conflicting requirements from today's products. First, he requires a product which is easy to use, and freely available at a reasonable price, but on the other hand, he wants the product to be completely safe. Likewise, industry is subjected to opposing pressures. First, a competitive market requires that manufacturing costs be kept to a minimum, but responsibility to the consumer, maintenance of market share, and conformance to the law require the highest degree of built-in safety possible.

In order to find a common ground on which these conflicting positions can meet for the determination of safety standards and conformance thereto, it is necessary for industry and the consumer to carefully examine their objectives and requirements for product safety.

First, industry must have as its primary objective good initial design quality, compatible with existing technology, which addresses all possible causes of injury in both use and reasonable misuse, and all known product environments.

Second, industry must be devoted to good manufacturing codes which minimize product defects and ensure the detection of unacceptable defect levels prior to product being shipped.

Third, industry must ensure that its labelling, packaging, warnings, and consumer education fully informs the consumer of all risks inherent in product use or reasonable misuse.

The consumer for his part should:

- First: Be willing to exercise care and intelligence in the use and handling of the product, including adherence to appropriate use, maintenance and cautionary instructions provided by the manufacturer.
- Second: Be willing to accept that there is no such thing as absolute safety, and that levels of safety will vary with the state of technology for different products as well as consumer requirements for performance.
- Third: Be aware that there is always a finite (if small) probability of sustaining an injury when using almost any product.

If the above points are kept in mind, a rational approach to standards setting is possible, and acceptable sampling plans for conformance can be arrived at.

PRODUCT SAFETY STANDARD SETTING

The setting of a performance standard for consumer product safety requires three basic steps:
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- 1) Determining product performance characteristics which are regarded as safety related.
- 2) Defining precise methods of measuring the chosen characteristics on units of products.
- 3) Specifying the range of values of these measurements (i.e., limits) which are regarded as satisfactory from a safety point of view.

A fourth step which has been the subject of much discussion and controversy over the past few years is:

- 4) Development of methods for assuring compliance to the standard.

A paper by the National Bureau of Standards⁽¹⁾ discusses five methods of ensuring compliance, viz:

- 1) Processing of complaints of injury and defective products.
- 2) Market place sampling of products.
- 3) Voluntary in-plant sampling or other Quality Control Assurance by the producer.
- 4) Mandatory in-plant sampling prescribed by the regulator.
- 5) Prototype testing prior to production.

The last four of these methods require testing and therefore sampling of the product.

CHOICE OF SAFETY LIMITS

The following discussion lists the main issues involved in the initial setting of safety limits in the standard, insofar as they are relevant to the specification of sampling schemes. Some sampling plans and schemes are then described which can help to overcome some of the problems encountered.

The main issues which cause difficulty in the actual setting of safety limits, and methods of sampling to ensure conformance, are as follows:

- 1) The actual test methods and environmental conditions under which the tests are carried out cannot duplicate the wide range of real product use (or mis-use) conditions and environments. They are only approximations to real life.
- 2) There is usually no unique point on the scale of measurement for a particular characteristic which defines the line between safe and unsafe. Rather, there is more likely to be a gradual gradation from safe to unsafe along the scale of measurement.
- 3) The relationship between the scale of measurement and level of safety (or probability of accident) is not directly measurable, and is rarely, if ever, known with any exactitude. In other words, although we would like to be able to plot the curve in Figure 1, we cannot do so.

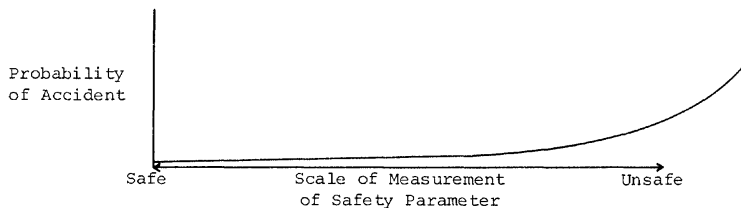


FIGURE 1

- 4) The above lack of knowledge is further complicated by the lack of precisely measurable information on the probability and severity of injuries arising from given accidents, and the accident scenario.
- 5) Optimum product performance is not usually at the point of minimum probability of accident, and optimum product performance is not the same for all

consumers. There is often an average desirable product performance \bar{P} , and a P_{\max} and P_{\min} , thus:

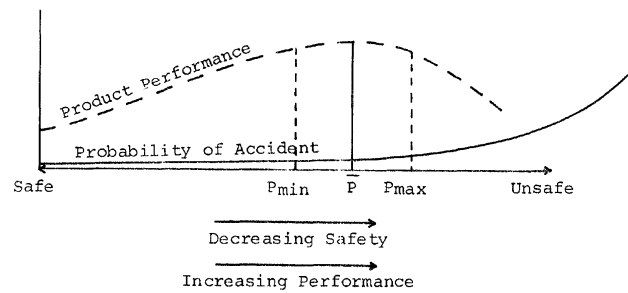


FIGURE 2

- 6) Minimum product cost is not usually at the point of minimum probability of accidents, thus:

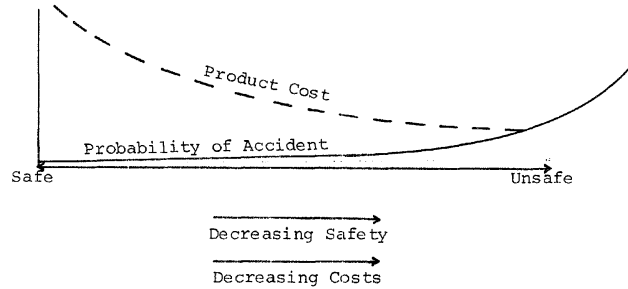


FIGURE 3

- 7) In addition to the variability of consumer requirements for performance, there is variability of the product being manufactured. This manifests itself in two ways: first, as a distribution of values about some chosen target value, and second, the possible occurrence of mavericks, as shown in Figure 4.

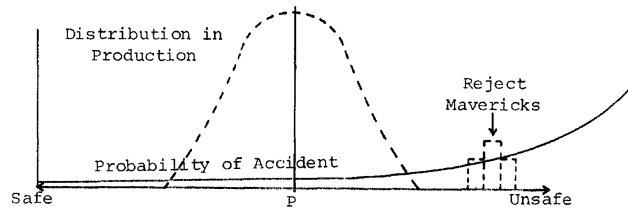


FIGURE 4

- 8) The amount of variability may be further increased during the life of the product, due to ageing or storage effects.

Bearing the above considerations in mind, it will be apparent that the determination of the safety limits is very much a matter of judgement, and will usually be a balance between performance requirements, technological and manufacturing capabilities, and attainment of an acceptable safety level.

It is usual to choose a limit (L) so that there is only a small risk of accident below it, and at most only a small percentage of product made above it.

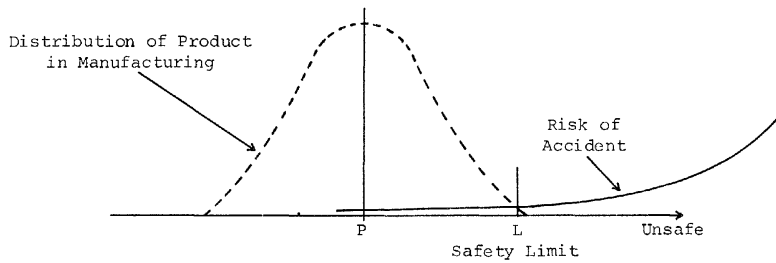


FIGURE 5

If this proves impossible, then either the target value, P, has to be moved down (at the expense of performance), or production variability has to be reduced, to the point where a consumer acceptable limit is obtained.

So long as each specific limit in a safety standard is set with these considerations in mind, consumers and regulatory agencies must recognize that some units of mass produced product which exceeded the limit will reach the market, but that these units do not represent a sudden jump from absolute safety to substantial hazard. The producer for his part must ensure that the risk of accident is kept to an absolute minimum compatible with:

- 1) Consumer requirements for performance, which will determine the target or average value of the product distribution.
- 2) The state of technology underlying design, which will determine both the location and spread of the distribution.
- 3) The capability of manufacturing processes and materials in avoiding defects which fall outside the distribution.

SAMPLING PLANS FOR USE WITH SAFETY STANDARDS

There has been much discussion in recent years concerning the part that sampling plans should or should not play in safety standards. This audience is probably familiar with many of the diverse opinions which have been aired on this topic. Some insist that nothing less than 100% compliance is satisfactory, while others would settle for large sample/zero defect sampling plans. There are also those who argue for more practicable small samples and allowable defects. Whether or not sampling plans should be included in safety standards is also a debatable issue, but that it is necessary to use well thought out sampling plans for checking conformance to standards is undeniable. I am going to discuss three types of sampling plans which, if used separately or in combination, would contribute to a balanced compromise between the above mentioned extreme points of view, and show how a judicious use of available sampling technology can be brought to bear on an urgent technical and social problem.

The three types of plans I will discuss are:

- 1) Three Class Attribute Plans.
- 2) Normal/Tightened/Reduced Plans.
- 3) Dodge & Romig type AOQL Plans.

THREE CLASS ATTRIBUTE SAMPLING PLANS FOR SAFETY STANDARDS⁽²⁾

The main advantage which 3-class attribute plans have in sampling for safety is the recognition of a "marginal zone" between "good" and "bad" product. In sampling for safety, this marginal zone can be considered as the "safety margin" between "relatively safe" and "relatively unsafe" product. A given proportion of product can then be tolerated within this "safety margin" zone. This proportion can be kept below agreed levels by normal Quality Control methods and compliance can be judged using relatively small sample sizes with non-zero acceptance numbers. In addition, it is accepted that any product in the "relatively unsafe" zone is unacceptable, and no defects of this kind are allowed in the sample.

Diagrammatically:

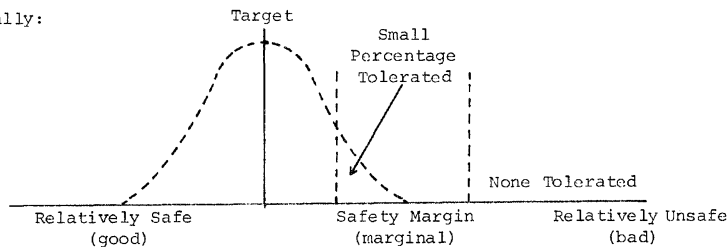


FIGURE 6

In a sense, the safety limit becomes a zone rather than a hard and fast line of demarcation, but the scheme still retains a harsh zero defect control on product that is outside this zone. Thus, these plans provide a nice combination of control at the margin and protection against extremes.

It is possible to visualize cases where high quality levels could be maintained using large sample sizes, and small (non-zero) acceptance numbers for bad product, but this paper will deal only with schemes which allow zero defects in the bad zone.

Consider as an example the following plan.

Sample size	=	10
Allowable marginals	=	2
Allowable bad	=	0

The set of operating characteristic curves for this scheme are given in Figure 7. The curves show how the probability of acceptance varies jointly with the percentages of marginal and bad product in the batch. With 8.5% marginal and zero bad, the probability of acceptance is 0.95. However, the plan reacts quickly to fail batches containing even low proportions of bad material, but passes most batches with lowish quantities of marginal product.

Thus, assuming a producer is controlling the mean and spread of his distribution, a shift of either in the wrong direction will be detected by increasing quantities of marginal product, and this would provide a warning to both the producer and the regulatory agency without incurring the penalty of failing an inordinate number of batches.

On the other hand, a sudden occurrence of gross defects (mavericks) which were not part of the general distribution would be detected quickly.

Other plans with sample sizes up to 150 are given in Reference 2, and these show that by a judicious choice of acceptance numbers for marginals, the operating characteristics can be moved to the left or right and steepened. Of course, as the sample size increases, the plans become increasingly harsher on bad product.

NORMAL/TIGHTENED PLANS

The three class attribute plans described above can be further modified by using an appropriate normal/tightened strategy. The strategy adopted will depend on how critical the characteristic is to product safety, as well as the economics of sampling and testing. For example, if a particular limit is considered highly critical to safety, but testing is destructive and expensive, a tightened/normal/tightened system as follows might be considered:

	<u>n</u>	<u>Acceptance #</u> <u>Marginals</u>	<u>Switching Instructions</u>
Tightened	60	12	Switch to normal after 5 acceptable batches.
Normal	10	2	Switch to tightened if 2 out of 5 consecutive batches rejected.

The operating characteristic is shown in Figure 8.

This plan is much harsher to bad product than the normal plan above, and also more discriminating between low and high percentages of marginal product.

Of course, it is only possible to use such normal/tightened plans where production is continuous, and where the producer is doing the actual sampling and testing on site.

AVERAGE OUTGOING QUALITY LIMIT (AOQL) PLANS

As the main object of the above plans is to ensure that only a minimum proportion of product in the safety margin zone reaches the market, there is merit in using an approach similar to that contained in Dodge & Romig tables⁽³⁾ in which an AOQL for marginals is agreed upon and the level of sampling is determined by the process average of production and lot size. Such schemes recognize that different production processes will produce different levels of percent defective, and they provide an economic stimulus to the good producer by requiring lower sample sizes when the process average is lower. It is usually felt that 100% screening of rejected lots is a prerequisite to the use of the AOQL concept. However, as Dodge & Romig have pointed out, product having a percent defective moderately higher than say 1.5 times the AOQL will suffer sufficient rejections to force the producer to undertake corrective action to improve his quality. Thus, together with potential economics in sampling, there is a double pressure on the producer to get his quality well above that called for by the AOQL.

There is no reason why Dodge & Romig and 3 class attribute schemes should not be combined. In such schemes the allowable number of units in the bad zone would still be zero, and the sample size and acceptance number for marginal product would be determined from Dodge & Romig tables. The operating characteristics given in the tables would then apply to the zero percent bad condition.

For example, if up to 15% "marginal" product was considered acceptable, and a producer had a good history of producing virtually no bad products, the following plan adapted from Dodge & Romig Sampling Inspection Tables could be used.

Batch Size = 50,000 - 100,000

n	C ₁	C ₂	Marginal Process Average %	Bad Process Average %	Marginal AOQL %	Probability of Accepting Process Average Batches	P(.15)
14	2	0	0-0.2	0	10	.99	.65
19	3	0	0.2-2	0	10	.99	.69
44	7	0	2-4	0	10	.99	.66
80	12	0	4-6	0	10	.99	.64
155	22	0	6-8	0	10	.99	.50
260	35	0	8-10	0	10	.99-.96	.29

n = Sample size

C₁ = Acceptance number for marginal product

C₂ = Acceptance number for bad product

P(.15) = Probability of accepting batches containing 15% marginal product.

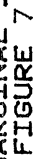
This plan has the following advantages, it:

- 1) Requires low sample sizes when process average for marginals is low.
- 2) Provides a very high probability of acceptance when process average for marginals is maintained.
- 3) Forces action for improvement by rejecting more than 1 out of 3 batches when marginal product exceeds 15%.
- 4) Produces an AOQL of 10% marginals if rejected batches are screened.
- 5) Results in minimal total inspection when rejected batches are screened.
- 6) In general, encourages producers to keep distributions of important safety parameters well within the safety limits.
- 7) Gives more stringent protection against accepting bad product, as process average for marginals worsens.

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THREE CLASS ATTRIBUTE TIGHTENED: NORMAL PLAN

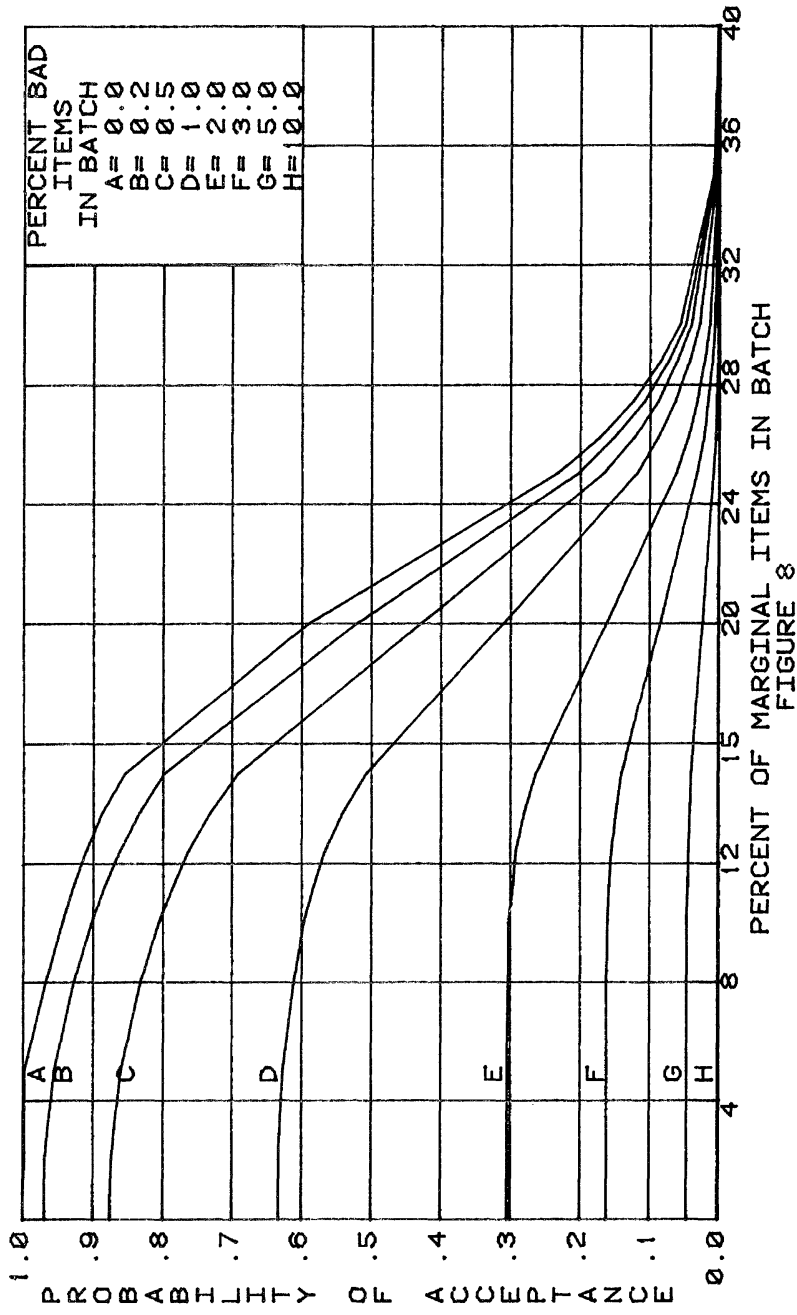


FIGURE 8

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In order to set the stage for this paper, I will very briefly describe AHAM's standards development activities.

First, AHAM develops product performance standards for home appliance products. A few of these are simply standard methods for measuring performance; others, in addition to being test methods for measuring performance, prescribe some realistic recommended levels of performance. See AHAM "Index of Standards", Figure 1.

FIGURE 1

AHAM PUBLISHED STANDARDS

- | | |
|--|---|
| DH-1 — Dehumidifiers, Self-Contained, Electrically Operated, Mechanically Refrigerated (American National Standard B149.1-1972) | HU-1A — Humidifier Application Standard |
| ER-1 — Household Electric Ranges (American National Standard C71.1-1972) | RAC-1 — Room Air Conditioner Standard (American National Standard Z234.1-1972) |
| ER-2 — Household Electric Ranges with Glass/Ceramic Cooking Tops (American National Standard C71.1a-1975) | RAC-2SR — Room Air Conditioner Sound Rating Standard |
| ER-3 — Cleaning Performance of Household Electric Ranges with One or More Pyrolytic Self-Cleaning Ovens (American National Standard C71.1b-1975) | DW-2PR — Plumbing Requirements for Household Dishwashers (American National Standard A197.1-1973) |
| HLD-1 — Standard Methods of Measuring Household Tumble Type Clothes Dryer Performance (American National Standard A197.6-1975) | HLW-2PR — Plumbing Requirements for Home Laundry Equipment (American National Standard A197.2-1973) |
| *HLD-2EC — Test Method for Measuring Energy Consumption of Household Tumble Type Clothes Dryers | FWD-2PR — Plumbing Requirements for Household Food Waste Disposer Units (American National Standard A197.3-1973) |
| HLW-1 — Performance Evaluation Procedure for Household Washers (American National Standard Z224.1-1971) | FWD-1 — Standard Methods of Measuring Household Food Waste Disposer Performance (American National Standard A197.4-1974) |
| *HLW-2EC — Test Method for Measuring Energy Consumption of Household Clothes Washers | TC-1 — Performance Evaluation Procedure for Household Trash Compactors (American National Standard A197.7-1976) |
| HRF-2-ECFT — Test Procedure to Determine the Freezer Temperature and Energy Consumption of Household Refrigerators, Combination Refrigerator-Freezers, and Household Freezers | *CO-1 — Household Electric Can Openers |
| DW-1 — Household Electric Dishwashers (American National Standard A197.5-1975) | *CM-1 — Household Electric Coffeemakers |
| HU-1 — Appliance Humidifier Standard (American National Standard Z235.1-1972) | *FB-1 — Household Electric Food Blenders |
| | *FP-1 — Household Electric Fry Pans |
| | *I-1 — Household Electric Irons |
| | T-1 — Household Electric Toasters (ANS C70.6-1977) |
| | *WBSG-1 — Household Electric Waffle Bakers and Sandwich Grills |

STANDARDS UNDER DEVELOPMENT

- | | |
|--|---|
| Performance Evaluation Procedure for Microwave Cooking Appliances | Household Electric Slicing Knives |
| Room Air Conditioner Sound Application Standard | Refrigerator-Freezer Standard and Recommended Levels of Performance |
| Household Electric Hair Dryers | Sound Measurement and Rating Standard for All Appliances |
| Household Electric Chafing Dishes, Fondues, Deep Fat Fryers, Saucepans and Dutch Ovens | Method for Measuring Energy Consumption of Household Dishwashers |
| Household Electric Food Mixers | Household Electric Curling/Styling Wands |
| Dishwasher Drying Performance Standard | Household Electric Slow Cookers |
| Test Method for Measuring Energy Consumption of Electric and Gas Ovens and Surface Units and Microwave Ovens | Household Electric Toasters/Broiler Ovens |
| Room Air Conditioner Hours of Operation | Household Electric Clocks |

*Pending approval as American National Standard

Second, the Association also develops safety standards but these are called "safety recommendations" because they are developed for the sole purpose to recommend their consideration for use by the independent safety testing laboratories, Underwriters Laboratories Inc., and the American Gas Association Laboratories.

Everything done by a trade association because of participation by competitors is sensitive to antitrust laws. Thus participation in these activities must be voluntary. Those who participate in standards development work do so voluntarily and anyone has the choice of using the standards in whole or in part or not at all.

Virtually every electric home appliance manufactured in the United States is tested and listed by Underwriters Laboratories Inc., and gas appliances are tested and approved by American Gas Association Laboratories to assure that these products are prudently safe. AHAM recommends that its members submit their products to these independent laboratories rather than "marking their own papers"; manufacturers should have experts besides their own in appraising the safety of their products.

I will not describe the detailed process of developing standards within AHAM and the steps standards must pass through all the way to its Board of Directors before they can be AHAM standards. The Policy and Procedures Governing Standards state that once this is accomplished, standards must be approved by all interested parties outside of AHAM through a consensus process and ultimately be recognized as American National Standards. The safety recommendations to the independent safety laboratories proceed through their consensus procedures until they too are recognized in some form as American National Standards.

THE CHANGING USES OF STANDARDS

Having provided this brief background, it will be interesting to note how the role of product standards has changed until their present day use. Fifteen years ago standards, both for performance and safety, were used solely for the purpose of providing manufacturers with a common laboratory test for the evaluation of their products. Using these procedures a manufacturer determined how his product and any stage of its development ranked with his competitors and knew that his competitors determined the performance levels of their own products along with their mutual competitors the same way to arrive at the same results. This use of home appliance product standards has not changed and will not change in the foreseeable future.

With additional uses these standards have become more sophisticated, more generally recognized and more universally used by government, both at the federal and local levels, by consumer organizations, by consumer magazines, and generally by anyone who uses or prescribes the testing of a product. Although engineering lab tests 15 or more years ago were used in developing a product which was acceptable to the consumer, engineering tests had to become more consumer oriented. These test procedures had to be developed so that the demands on the product in the laboratory were more directly comparable with the demands to which the product was exposed during consumer use.

Until recently, standards provided an adequate means for determining energy consumption of home appliances when tested in a laboratory. Often a product ranking was all that was necessary. With energy now a very serious issue, these laboratory test procedures must more realistically portray ways a consumer uses the product or be directly correlative to the results of the energy use of that product while being used by the consumer. This will be dealt with in more detail later in this paper.

AHAM'S CERTIFICATION PROGRAMS

These standards, particularly the standard methods for measuring performance, are directly applied to AHAM's certification programs.

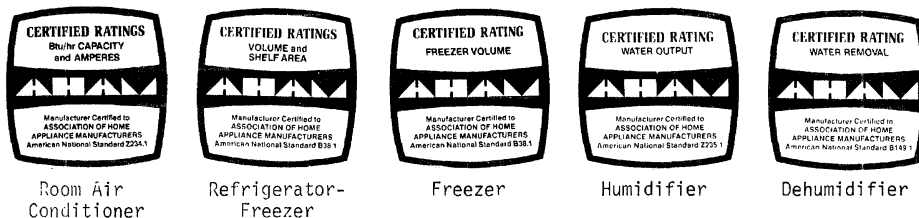
Through the use of an independent laboratory under contract to AHAM, AHAM verifies manufacturer certified ratings of the cooling capacity of room air conditioners. Until very recently, the energy efficiency ratio of room air conditioners was listed along with the certified cooling capacity and the certified watts of each room air conditioner but the regulations developed by the Department of Energy (DOE) have brought about at least temporarily a conflict which can no longer permit publishing these energy ratings. The reason for this will be made clear when we describe the DOE sampling plan.

The cubic foot refrigerator volume and freezer volume and the shelf area of refrigerators and freezers and until recently the energy consumption were certified

under the AHAM Refrigerator-Freezer Certification Program. The output capacity in gallons of water per 24 hours for humidifiers is certified and the water removal capacity rating in pints per 24 hours for dehumidifiers is similarly certified.

To enter the certification programs, a manufacturer or private brand labeler signs a contract with AHAM which requires among many other things that he purchases certification seals, see Figure 2, and affixes one to each of his products.

FIGURE 2



If he enters into any one of these four certification programs, every product that he manufactures covered by that program must be certified. He cannot certify certain models of room air conditioners, for example, without certifying others. It may be interesting to note that the purchase price of these seals covers the total cost for the operation of this program, the administration of the program, the testing, etc.

GOVERNMENT USE OF HOME APPLIANCE STANDARDS

The General Services Administration (GSA) references AHAM standards in its procurement specifications for all government purchases of home appliances. State government agencies also require that certain products purchased be tested according to their respective AHAM standards.

Any organization evaluating a product or a component, especially today, that has a desire to reduce the energy consumption to make home appliances more efficient can only determine the authentic efficiency improvement or reduction in energy use by applying that product to these nationally and often internationally recognized standards.

AHAM standards for the measurement of energy were developed as a result of very complex field testing of home appliances under actual use in hundreds of homes.

The Department of Commerce's (DOC) voluntary energy program developed some four years ago provided that the energy consumption measured according to these standards appear on a label with the product at the point of sale. The label contained both the AHAM certification seal and the DOC program seal on room air conditioners. In addition to room air conditioners, the program had advanced to the extent of formalization for refrigerators and freezers also using the AHAM standards when in December, 1975, in spite of the fact that the voluntary program had gotten under way in short order and was already working very well, the Energy Policy and Conservation Act was passed.

This Act required that by 1980 the energy efficiency of appliances had to improve at least some 20% over the energy efficiency values of 1972 and that these home appliances had to be labeled with their annual cost of energy and that standards had to be developed to measure these energy efficiencies and their annual energy consumption.

Over two years later, mostly as a result of bureaucratic bungling some of which I will describe because of its interest to people with knowledge of statistics and quality control methods, has provided no tangible results--products still are not labeled with the energy values although the DOC voluntary program was effectively working for the purpose of energy conservation and provided the opportunity for consumers to save energy and money. The passing of the Act in December, 1975 formally suspended the voluntary program.

Last year our administration in Washington proposed amendments to this Act. Whether good or bad, these amendments (not legislated at this writing) have further delayed the implementation of the program. My guess is it will be at least another two years until the program becomes fully effective.

THE DEPARTMENT OF ENERGY SAMPLING PLAN

The test procedures finally adopted by the DOE are indeed the AHAM test procedures with little if any change. For a number of products, room air conditioners and refrigerators particularly, the tests are very cumbersome. A single test for refrigerators takes weeks although a number of refrigerators can be tested simultaneously.

This sounds like a condemnation of the AHAM standards. It is not. These AHAM test procedures are very precise and closely controlled tests that are used in the development of a product and for random quality control production testing on an infrequent basis to determine precisely the energy consumption of these products. Manufacturers have developed and use simpler test procedures, shortcuts if you will, to determine quickly if the performance of their product would correlate with the performance if the same product were tested according to the complex AHAM test procedure. In some cases these shorter tests can be conducted on every product as it nears the end of its production line.

When these test procedures were submitted both for the use in the DOE voluntary energy program and to meet the requirements of the Energy Policy and Conservation Act of 1975, industry expected as was the case with the DOE voluntary program that these test procedures would be used for exactly what they are intended for--the precise method of measurement.

The DOE, then the Federal Energy Administration (FEA), when publishing the test procedures added to the AHAM test procedure a sampling plan.

The DOE sampling plan states that

" (f) Room air conditioners.--(1) Except as provided in paragraph (f)(4) of this paragraph, no manufacturer, distributor, retailer, or private labeler of room air conditioners may make any representation with respect to or based upon a measure or measures of energy consumption described in §430.22(f) unless a sample of sufficient size of each basic model for which such representation is made has been tested in accordance with applicable provisions of this subpart such that, for each such measure of energy consumption, there is a probability of not less than 0.95 that the means of the sample is within ± 5 percent of the estimate of the true mean of such measures of the basic model."

This sampling plan was the one dictated by the DOE for every appliance regulated by the Act with only slight variations in the ± 5 percent of the estimated true mean. Where the DOE has decided that the coefficient of variation is wider and more difficult to control as it is for refrigerators, for example, ± 10 percent is allowed; there are very few such exceptions.

At least three samples of every basic model must be tested and they must be tested using the complex AHAM test procedure, no correlative or shorter test procedure may be used.

The industry's major objection to this sampling plan is the fact that it does not control product energy consumption variation; it requires only that sufficient units be tested until the mean of the sample is within ± 5 percent of the estimate of the true mean of total production.

Where energy consumption is certified under the AHAM program for room air conditioners and refrigerator-freezers, a tolerancing system is prescribed which will not permit any unit that is produced to consume more than 110 percent of its certified energy value.

Figure 3 is a comparison of technical issues between the appliance industry's tolerancing system for ratings and the FEA's sampling system for determining ratings. The conflict between the DOE sampling plan and the tolerancing system used by the AHAM certification programs is the basis for the need to stop certifying and listing in AHAM Certification Directories the energy consumption for room air conditioners. As Figure 3 indicates, among other things, the value arrived at by the AHAM tolerancing system could very well be different from the value arrived at by the DOE sampling plan. The DOE regulation states in effect in §430.24(f) that no energy representation may be made for a product unless it is based on the test procedure and sampling plan issued by the DOE. The energy consumption value arrived at by the AHAM certification program and the one arrived at by the DOE sampling plan may be sufficiently different

If it meets the DOE requirements, it would not meet the requirements of the AHAM certification program and more importantly to manufacturers, because of the federal law, the situation could very well be vice versa. To make things worse, the requirements of the California state law are indeed at the moment different from those required by the federal law.

FIGURE 3

Comparison of the Technical Issues Between the Appliance Industry's Tolerancing System for Ratings and the FEA's Sampling System for Determining Ratings

<u>Tolerancing System</u>	<u>Sampling System</u>	<u>Consequences of Sampling Plan</u>
1. Allows manufacturers to choose the rating - gives flexibility in establishing rating.	1. Establishes rating based on rigid mathematics.	1. Rating is likely to be incorrect for a given model.
2. Restricts production variability.	2. Places no control on production variability.	2. Rating could be deceptive to consumer (because consumer only buys one model and it is likely not to be the average).
3. Assures consumer that the unit purchased will not exceed an upper limit on energy consumption.	3. Assures only that the average of all units will be within a specified limit of the population mean. (Assuming the sample tested is truly representative of production.)	3. Relates to #2 i.e., possible consumer deception.
4. Since the manufacturers have flexibility, when establishing ratings, correlative testing (less complex, less expensive) can be used. Correlative testing is an inherent part of the tolerancing system because this system does not restrict the method of establishing the rated values.	4. Correlative testing is presently not allowed and would have to be specifically included for establishing ratings.	4. For room air conditioner and refrigerator-freezer, lack of correlative testing is an economic hardship because of expensive facility requirements (especially for room air conditioners) and long duration of test (especially for refrigerator-freezers). This does not apply for most other AHAM products.
5. Lends itself to less complex Q.C. procedures to be certain that the rating is maintained because the rating has only an upper end limit.	5. Sampling plan does not lend itself to Q.C. procedures because it addresses itself to the total population mean.	5. Manufacturers must have a Q.C. system to market an acceptable product. Applying the sampling plan technique to Q.C. would be an added burden (particularly to room air conditioners and refrigerator-freezers and to varying degrees to other products).
6. The tolerance system allows manufacturers to select rating based on testing and experience and allows him to adjust the test value based on any anticipated variability in production.	6. Sampling plan is an inaccurate method of arriving at the rating because it assumes that the sample (which must be early production or pre-production) is representative of all products that will be produced and contains all the variances likely to be encountered during production of that model. (All these assumptions are known to be false for room air conditioners.)	6. Sampling plan may result in inaccurate ratings (particularly true for room air conditioners and refrigerator-freezers and to a lesser degree to other AHAM products).
7. Tolerancing system allows manufacturers to conservatively rate product because it has only a one ended tolerance.	7. Sampling plan requires rating at mean of sample. It does not provide any means for adjusting values based on past experience.	7. Same as #6.

Room Air Conditioner Industry's Specific Concerns

Room air conditioner manufacturers do not have confidence in the rating established under the sampling plan because:

- It requires rating at the mean (a very rigid number),
- It does not provide a system for adjusting the initial rating as production variation changes,
- additional testing after establishment of initial value (although not required) could cause initial rating to become suspect as wrong,
- In order to determine if the initial rating is right or wrong a significant number of units (30 to 40) would have to be tested.

Aside from the fact that the DOE sampling plan has no requirements on product variability with regard to energy consumption, a product must be rated before production actually begins or certainly before any energy representation is made and the sampling plan assumes that the sample tested is truly representative of production. On products such as home appliances I can assure you that a product manufactured during a year or two year period can have some variation in the measured energy use. The AHAM certification program provides a realistic tolerance; over its full range the consumer is protected fairly. The DOE program does little, if anything, to control this variation and once a product's energy consumption is so rated there is no provision to change this rating regardless of any variation that may occur throughout the period the model may continue in production. After your analysis of Figure 3, we'd be interested in your evaluation of the two systems.

All of this may be similarly true for refrigerators but at this writing, because the complex testing is of such long duration some manufacturers do not have test results for all of their models. Thus it is not known whether there is a conflict with numbers nor are the numbers available for publication in the Certification Directory if there will be no conflict.

Until the differences between the two programs can be resolved, any valuable purpose that the AHAM certification programs provided the consumer has passed on to oblivion. The DOE has been informed of all of this and is not willing to bend or change its position. With energy a critical issue the government has stopped two important programs which were in place serving the consumer with vital energy information for four years.

THE VOLUNTARY STANDARDS SYSTEM IN THE UNITED STATES

As you are aware, the procedure used by the Association of Home Appliance Manufacturers for developing standards requires a consensus agreement by all interested parties outside of AHAM so that these standards can be recognized nationally and internationally as American National Standards. This procedure varies little from those used by other voluntary standards developers. Until now, whenever any government agency had a use for these standards, instead of developing new and different ones, it recognized standards that were developed by the experts, and it has been generally recognized that the expertise does indeed lie within the private sector of industry. Certainly no one understands home appliances more intimately than the engineers who have designed, developed, tested and manufactured them.

I believe that those of you who are involved in the voluntary standards development system are aware of the fact that the government wants to take over, set up rules and regulations, making it practically impossible for an organization such as AHAM to continue to develop good standards for home appliances, universally recognized standards.

You should be familiar with the content of Senate Bill 825, The Voluntary Standards and Accreditation Act of 1977, "a bill to foster competition and consumer protection policies in the development of product standards, the testing and certification of products, and for other purposes" introduced March 1, 1977 by Senator Abourezk.

Very briefly this proposed legislation:

1. provides for the Federal Trade Commission (FTC) to develop guidelines which all standards development organizations must follow;
2. establishes an Institute of Standards within the National Bureau of Standards (NBS) to act as an advisor to FTC and to write standards if not done elsewhere according to requirements determined by FTC;
3. places the DOC in charge of international standards participation by the United States;
4. establishes a National Laboratory Accreditation System;
5. establishes a National Standards Management Board to "oversee" all standards activities in the United States. This replaces the American National Standards Institute (ANSI).

S.825 was not enacted last year; whether it might be enacted in the future is now only of academic interest because various government agencies are adopting the basic

policies and procedures spelled out in S.825 such that any standard developed by the private sector must prescribe to the rules spelled out in S.825 if they are to be used by a government agency.

In July, 1977, the DOC developed a lengthy report which it submitted to the Office of Management and Budget (OMB) which seriously impugns the existing voluntary standards and testing laboratories systems in the United States. The report has a section called "Horror Stories" related to standardization and certification activities. Most of these "stories" were based on complaints from parties with self-serving interests, most were not investigated and were exaggerations, not factual or contained only innuendos.

The DOE now has a public law on its acceptance of standards developed by the private sector. This public law includes again most of the requirements of S.825. I have been called by DOE lawyers on occasion who are considering the use of AHAM standards and have been asked questions such as to identify, for example, the distributors or retailers who participated in the standard development committees. It is very difficult to explain to these lawyers that a distributor or dealer is not interested in spending their time developing product standards because their time can only be used productively selling their product. This is a fact of life and something that I don't believe can be forced even by regulation. The only obvious alternative is the development of these standards by government and government alone and apparently that is the reason for imposing these requirements in the first place.

Finally, the OMB published in the January 3, 1978 Federal Register a proposed OMB circular on federal agencies interaction with and use of voluntary consensus standards-developing bodies. This again imposes many of the requirements as proposed in S.825, The Voluntary Standards and Accreditation Act of 1977, and I believe that unless this circular is changed substantially, there is no way that AHAM, for example, as a voluntary standards developer can, no matter how intent it may be to meet the requirements of this circular, continue to be a developer of home appliance "voluntary" standards.

The very same standards that government found acceptable are no longer acceptable because they may not have been developed according to a new set of government regulations.

LCS 030:60:886

THE JCPENNEY COLOR-CODING PROGRAM FOR TEXTILES

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INTRODUCTION

The purpose of the color-coding system is to minimize customer returns for reasons of color variations (off shade, too weak, too heavy) of curtain, drapery, and bedspread ensemble items available through the JCPenney catalogs.

Our suppliers compare and evaluate all new production of dye/print lots against an approved standard and have been instructed to ship to us only the merchandise that falls within the established limits of tolerance of the color-coding system.

DESCRIPTION OF THE COLOR-CODING SYSTEM

The color-coding system as devised and implemented by JCPenney is based on the visual, subjective comparison and evaluation of new dye/print lots of textile fabrics versus a standard under controlled lighting conditions to determine their degree of sameness or difference with respect to shade and strength.

New lots of white, dyed or printed fabrics of the same style, color/design are evaluated against an approved standard and are rated acceptable or not acceptable within the established limits of tolerance. Unacceptable merchandise received at a JCPenney Catalog Distribution Center is returned to the supplier.

The color-coding procedure is comparatively simple and straightforward to carry out. The range of acceptable tolerances of new dye/print lots to standard is quite broad and reasonable.

The technique for the color-coding of textiles is similar to that used for the evaluation of colorfastness tests (light exposure, washing, dry cleaning, etc.) where the test sample is visually compared to a standard for degree of shade change and is assigned a numerical rating.

Individuals involved in the color-coding of fabrics must have an aptitude for color judgement and be free from color deficiencies. There are testing methods available for determining a person's color aptitude and/or color deficiency.

The in-process controls and standardization methods employed by most dye houses provide a flow of dyed and printed goods that fall well within the limits of tolerance of the color-coding system and can be readily coded when received by our suppliers.

PROCEDURE FOR COLOR-CODING

The Standard 50

The approved standard shade - white, dyed or printed, is arbitrarily assigned the code number 50.

The Standard 50 is placed on a flat surface with a neutral grey background under the recommended (artificial daylight) viewing light.

The new dye/print lot to be evaluated is placed alongside of (abutting but, not overlapping) the Standard 50.

The Evaluation

The comparison of the new lot with the Standard 50 and assignment of the color-code number.

Color-Code 50 - - - -

New lots that are found to be the same shade and strength as the Standard 50 (or with just a nuance of difference) are coded 50.

Color-Code 45 - - - -

New lots that are found to be slightly weaker in strength but, on shade to the Standard 50 (could be shipped with items coded 50 and be acceptable to most customers) are coded 45.

Color-Code 55 - - - -

New lots that are found to be slightly heavier in strength but, on shade to the Standard 50 (could be shipped with items coded 50 and be acceptable to most customers) are coded 55.

Code UC (Unacceptable) - - - -

New lots that are found to be noticeably weaker in strength to the Standard 50 (fall outside the limits of tolerance, rate below 45, could not reasonably be shipped to a customer with items coded 50) cannot be color-coded and are therefore unacceptable.

New lots that are found to be noticeably heavier in strength to the Standard 50 (fall outside the limits of tolerance, rate above 55, could not reasonably be shipped to a customer with items coded 50) cannot be color-coded and are therefore unacceptable.

New lots with noticeable variations in shades (redder, yellower, bluer, etc.) to Standard 50 are considered to be mismatched shades that cannot be color-coded and are therefore unacceptable.

Note: Trim - fringe, tassels, braid, rickrack, embroidery, etc. are also evaluated for conformity to standard. The overall color of a fabric may be satisfactory and codeable but, not be acceptable due to noticeable and objectionable shade differences in the applied decorations.

The color-coding method is applicable only to those fabrics of the same fiber composition, construction, color and finish. Related items of similar color and design but, of different fiber and construction are offered as coordinates, not as true shade matches, the only prerequisite is that they be reasonably close in shade and strength as to harmonize satisfactorily within an ensemble.

Color measurement by instrumentation (colorimetry - spectrophotometry) can be used as an adjunct to the color-coding system but is limited almost exclusively, to the evaluation of solid shades and not prints or other multi-colored fabrics which account for over 80% of all textiles being coded.

COLOR-CODING TECHNIQUES

1. Fabrics under evaluation should be perfectly flat, free from wrinkles and folds.
2. Selvedges should be removed if they interfere in any way with the evaluation.
3. Swatch size should be at least 9X12 inches for solid shades. The size of printed fabrics should be large enough to contain all colors and elements of the design.
- 4 Check to see that both the standard and the new lot are face up; this will be obvious for printed fabrics but, sometimes in solid shades, differences are not as readily detected between the face and back of the fabric.
5. Align both the standard and the new lot in the same direction, i.e.: warp running lengthwise and the weft (filling) running horizontally. A ribbed fabric, such as a twill, should have the ribs running in the same direction.
6. Printed Fabrics - Printed fabrics of multi-colors and with intricate designs by their nature tend to camouflage shade differences. In evaluating a printed fabric or any cloth containing a design, the predominant feature (the background or the design) is the first to be compared to the standard. The secondary feature is then evaluated. Any unusual element of the design itself - a brilliant scarlet flower

for instance, that stands out in the overall print should be evaluated very carefully.

7. Sheer fabrics should be folded over so that the transparency of the material will not lead to erroneous results; a thickness of as many as eight layers may be necessary.

8. Plush fabrics are especially tricky to evaluate. The same fabric can appear to be completely different in shade (lighter-darker) depending upon the position in which it is placed and the way the light is reflected from the surface. The fabrics may have to be moved into various positions until a satisfactory alignment is obtained.

9. Metamerism, (apparent color changes caused by different sources of light) can be determined by changing the light source momentarily to incandescent/fluorescent but the color-coding itself is carried out under the daylight light only.

10. The presence of an optical brightener can be determined by examining the fabric under ultraviolet light. White fabrics are more likely to contain an optical brightener. If a new lot of white goods appears to be "whiter" than the standard or vice versa, it may be due to more complete bleaching of one fabric than the other or one may contain more optical brightener than the other. The ultraviolet light will readily establish this fact.

ORDER FILLING BY COLOR-CODING NUMBER

The suppliers have been instructed to place the color-code number on all individual packages of merchandise that they ship to our distribution centers.

Whenever feasible, the customer's orders are filled by picking from the bins, merchandise with like code numbers, i.e.: 45 with 45, 50 with 50, and 55 with 55.

If this is not possible then combinations of items coded 45 and 50 or 50 and 55 are picked for shipment to the customer.

Exception - curtain and drapery panels (where two or more may be hung side by side at a window or door) must have the same color-code designations.

Because of the very noticeable shade depth differences, items coded 45 and 55 in no instance can be shipped together on the same customer order.

LIGHTING REQUIREMENTS FOR COLOR-CODING

Artificial daylight is the recommended light source for carrying out all color-coding evaluations. The use of the same illumination in all color-coding areas ensures closer correlation and agreement of results among the various evaluators. The necessary lighting equipment is available from the Macbeth Corporation, the Diano Corporation as well as several other manufacturers of similar units.

Booth mounted installations provide a standardized viewing environment; therefore no consideration need be given to the surroundings. However, when a suspended overhead illuminator is used, it is very important that certain precautions be taken to ensure optimum results. Extraneous illumination (natural and artificial) must be avoided. The best location for the lighting unit is a windowless room. If the lamp is used for the lighting of a localized area, then this area or table should be shielded from extraneous illumination by a curtain. In this instance the curtain must be of a light neutral grey shade which in addition to shielding the special area from extraneous illumination, will provide a second important factor, a neutral grey (Munsell H-8 grey) background which is desirable to avoid brightness contrast and color reflections which might result if the curtain were anything but neutral. (For example, a violet sample reviewed in a blue surrounding will appear redder; a violet in a red surrounding bluer than it would appear in a neutral grey surrounding). All extraneous articles must be kept out of the color-coding viewing area at all times.

FABRIC STANDARDS - MAINTENANCE AND HANDLING

As recommended to JCPenney and supplier personnel, a file of approved reference standards of all dyed/printed curtains, drapery and bedspread ensemble items offered in our catalogs shall be maintained.

Since most fabrics age and change color over a period of time, reasonable care must be taken in protecting them from atmospheric degradation due to moisture, light, heat, fumes, dust, handling, etc. Standards should be stored in a thoroughly protected environment.

Suggested Storage Procedure:

One large fabric piece, minimum of 1 yard, coded 50 and identified as MASTER STANDARD, should be folded and placed in a plastic bag, (black preferably). The flap of the bag should be sealed with a strip of adhesive type tape. A label containing pertinent information should be affixed to the bag.

A smaller swatch of the standard (the working standard, used for routine inspection) should be kept in a separate plastic bag so that each time it's needed for color-coding, the master standard is not disturbed.

To reduce the possibility of soiling the standard swatches (oil from hands etc.) the swatches should be handled by means of a folded cardboard (file card) stapled to one side, or by clean disposable gloves.

For quick retrieval, the fabrics should be filed alphabetically by supplier, and in turn by style, color and catalog number.

The storage cabinet should be located in an area removed from any direct heat source.

Checking Standard for Color Change

Periodic comparisons should be made of the working standard and the master standard. If the working standard is found to have faded, become soiled or has changed color in any way, as compared to the master standard, it should be destroyed. A new cutting properly identified is then taken from the master standard for use in the routine evaluation.

To ensure that the master standard has not changed, colorimeter measurements should be made at the time of initial selection. The colorimeter measurements can be filed. At a later time the standard can be retested. If it is determined that the standard has faded or changed color in any manner, it can be replaced with a new one that corresponds with the original colorimeter measurements.

CONCLUSIONS

The color-coding system has eliminated obvious shade differences in merchandise that most certainly would have caused dissatisfaction if received by the customer.

The system has been in effect for over two years and it is accomplishing what it was designed to do - cut down the number of returns for reasons of shade variations, and in consequence has reduced unnecessary expenses and increased customer satisfaction.

As with any plan involving a number of people, cooperation is needed by all participants to make it maximally effective. Adherence to the requirements of the color-coding system will be mutually advantageous to the suppliers, to the JCPenney Company, and to the customer.

LCS 710:70:657

QUALITY CONTROL IN THE UPHOLSTERY INDUSTRY

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There are several descriptive statements which relate to the upholstered furniture industry:

- 1 - Historically, our industry has been a fashion-style-design oriented industry, not a technically oriented industry.
- 2 - In general, definitive, quantitative programs for the monitoring and assurance of quality-of-product have been virtually non-existent.
- 3 - To a great extent, the upholstery industry depends on its vendors for research and development.
- 4 - To a great extent, the upholstery industry accepts the "word of their vendors" concerning the quality of the materials the vendor delivers.
- 5 - Uniqueness of product doesn't last very long because of the "knock-off" concept; defined as "another company copying your design and then cheapening it"
- 6 - The industry is rife with small, low-overhead companies, who lack any quality consciousness, but who provide the same "aesthetic-look" at much lower prices.
- 7 - With respect to "product knowledge", upholstered furniture is one consumer product about which our consumers - and retailers - know very little.

Within the last five to ten years, a minor revolution has occurred in our industry. The revolutionary changes can be attributed to many factors, but here are a few of the more important ones:

- 1 - The germination and subsequent growth of "The Nader Movement".
- 2 - The increase in the amount of information for the consumer; consequently, our consumers are becoming better educated, more sophisticated buyers, and more quality and performance oriented.
- 3 - The growth of involvement of federal and state governments in consumer-product quality and performance.
- 4 - The hard-fact realization that programs which accurately monitor and assure product-quality also reduce cost and can increase profits!

Our company, Schnadig Corporation, recognized the needs many years ago, and then began to plan for implementation of a viable, thorough, and quantitative program for product-quality monitoring and assurance. At Schnadig this program is now called "Total Quality Assurance" (TQA). Our TQA program was originally complicated, somewhat, because our company has six upholstery plants scattered throughout the United States - all making essentially the same products. We also have three woodworking facilities in three different geographic locations.

TQA began with the realization of all the facts previously mentioned, and then TQA was implemented in three major areas:

- A - PSYCHOLOGICAL
- B - TECHNICAL
- C - ADMINISTRATIVE

PSYCHOLOGICAL

In our opinion, a quality program based solely on numerical and administrative entities will not work adequately. Quality psychology must permeate the entire organization; thus, TQA must begin and originate in the "board-rooms" and then flow unabated throughout the entire organization; then it will flow to our customers as another "end-product" of our company. The chairman of our board and corporate executive officers initiated and actively supported the "TQA attitude" and, ladies and gentlemen, regardless of how idealistic it may sound, the bottom line is very accurately simple ---- it works!

Just a side comment on idealism - it is high-time that our society returned to some "old-fashion", maybe "corny" idealism -- instead of the phony pseudosophistication that permeates our society today! Quality is an ideal; the psychology of quality should be idealism; and deviations should arise or occur only from the ideal - not from a compromise!

TECHNICAL

The technical part of our TQA program can best be described by two statements, in order:

1 - If the inside of a piece of upholstered furniture is made correctly, according to original, engineered specifications, the outside - including aesthetics and comfort - will inexorably be correct.

2 - Put a number on it! (Or at least try to.)

The technical part of our TQA program began by separating the needs in two areas, i.e. the control of the products we purchase (our raw materials) and the control of the processes we use to assemble the raw materials into our final product.

We found that our major problem was in the quality of our raw materials, particularly, in foams and padding materials, springs, and upholstery fabrics. Our next step was to develop first-generation specifications in the major-problem, raw-material areas. We then developed test methods in areas where none existed and used conventional test methods where supplier-user agreement could be attained.

We then developed raw-material sampling programs geared to yield data which when properly, statistically analyzed would: assist us in vendor performance rating; guide us in developing better specifications with reasonable tolerances; and guide us in the derivation of future sampling programs for routine, daily sampling.

The next step was the most complex step, i.e. the relation of all the information which we had previously developed to aesthetics and comfort.

With respect to "comfort", our sales and marketing group is attuned to our particular customer's definition of comfort and comfort ranges. Ranges of "comfort" were determined subjectively by our sales and marketing group, e.g. middle range of "just-right"; low end of good comfort range; high end of good comfort range; and so on. These samples were then taken to our labs where the measurable characteristics of the whole pieces and, after disassembly, the measurable characteristics of the components were determined, e.g. load-vs.-deflection, fabric breatheability, fabric stretch, spring loading, spring deflection characteristics, etc.

Once the measurable characteristics of the components were known - with their ranges - and once these characteristics and ranges were related to the whole, assembled piece of furniture, the next task was to relate this information to the specifications and tolerances determined in the first survey on raw materials.

We then contacted our vendors and outlined our needs as far as specifications and tolerances were concerned, and when our vendors saw documented evidence of our needs, cooperation was a matter of natural course.

Many of our raw materials, such as foams and springs, are used in vast volumes with exceptionally fast inventory turnover. These products had to be screened and tested in each individual plant. We designed and built the equipment for testing these products in each plant, and once the equipment was installed and operating,

statistical sampling plans were derived for each material at the volumes used in that particular plant.

Other raw materials are used in such volumes and rate in importance such that they are routinely sampled, and the samples are sent to the central testing labs for analysis.

Our TQA program on major raw materials includes:

lumber & wood composites	springs
finished KD frames	foams
adhesives	fabrics
assembled frames	buttons
plastic frame materials	deck fabrics

Our TQA program on minor raw materials includes all other materials used to manufacture our product.

The relation between raw material properties and final aesthetics is a little more difficult; however, remember the statement, if the inside is built properly, according to original, engineered specifications, the outside and final aesthetics will be correct. Attaining the "state of correctness" on the inside and thus the proper aesthetics outside is accomplished basically by two programs. The first of these programs involves training and educating our craftsmen in each step of the process by use of specification review meetings, photograph-drawing review meetings, and video tape sessions on the more complex steps or processes. For interest sake, permit me to interject here that Schnadig Corporation pioneered the use of in-house video systems (in our industry) for training our personnel. The second of these programs involves sampling and inspections of each step in the manufacturing process - from start to finish. Major areas of concern are outlined for the inspectors - as well as procedures for inspecting each step.

ADMINISTRATIVE

The routine administration of our TQA program involves:

- 1 - Ascertaining the proper flow of information and data
- 2 - Liaison with sales and marketing
- 3 - Ascertaining proper follow-up on field complaints and problems
- 4 - Planning the biannual meetings for individual plant TQA supervisors and production executives
- 5 - Liaison between design and merchandising
- 6 - Liaison between R & D, plant engineering, and product engineering
- 7 - Planning quality sessions with our customers
- 8 - Liaison between top-level, executive management, and other departments

I have, briefly and generally, outlined for you how our company has taken some giant strides forward in the area of quality assurance. We are cognizant of the fact that we are not yet as sophisticated or as statistically quantitative as many of your companies; but we are in the beginning stages, and we have shown a substantial "return" on our TQA investments to date. The "return" on our TQA investments more than justifies the present program, and these "returns" also justify program expansions and extension. Our goal is to, ultimately, have each raw material and each manufacturing process controlled by a sampling-inspection plan, which, by magnitude of confidence-interval, represents the importance of that raw-material or process to the total.

LCS 310:60:425

QUALITY COST AND PROFIT PERFORMANCE

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ABSTRACT

Use of failure cost (rather than total quality cost) as the principal financial measure of quality performance opens the door to more extensive and effective applications of this management tool. The measure is better correlated with other indicators of quality performance; the demonstrated correlation with profit performance forms a rational basis for quality cost performance norms; and the projected effect of a specific quality improvement on overall business performance can be forecast with better confidence.

BACKGROUND IN PIMS

From its earliest beginnings, the quality profession has engaged in the pursuit of profitable excellence. The list of searchers is as long as it is illustrious - Shewhart, Feigenbaum, Juran, and Schoeffler...Schoeffler? - While not a member of the quality community, he and his colleagues at Harvard broke the barrier that had prevented a direct coupling of quality costs to measures of business performance. (1) Prior to the landmark Profit Impact of Market Strategies (PIMS) study, quality cost methods, in general, utilized targets and emphasized prevention expenditures to reduce failure costs thereby bringing total quality costs into balance. In 1951, Feigenbaum wrote: "An unprofitable cycle is at work that operates something like this: the more defects produced, the higher the failure costs. The traditional answer to higher failure costs has been more inspection. This, of course, means a higher appraisal cost ... and the higher they go, the higher they are likely to go without preventive activity". (2) In the same book Feigenbaum says "... the product can be provided with those qualities which motivate purchase by the consumer and thus increase salability." As recently as 1970 Juran and Gryna recognized the problem of being unable to measure the effect of quality on business performance with these words: "The facts on cost of quality are often precisely ascertainable. However, facts on value of quality are more nebulous. In particular, while the factors of quality reputation and customer goodwill are conceded to be of great importance, the present methods for evaluating them are quite primitive." (3)

And there matters stood until the PIMS work was published in 1974. PIMS concluded, at least qualitatively, that the influence of Quality Reputation on Return on Investment was very potent indeed and second only to Market Share. Here, at last, was an analytic tool to couple quality to profitability.

The work reported in this paper was begun in 1975, and resulted from efforts to utilize the PIMS methodology to quantify the impact of quality on profitability. In order to achieve the quantification several criteria were established:

- (1) Provide a financial measure of quality performance that is consistent with other measures of quality performance;
- (2) Provide a measure which responds in a timely manner to changes in actual quality performance;
- (3) Provide a measure that is credible to Management, acceptable to the Controller organization, and suitable for inclusion in the routine financial reports of the business.

The primary data sources used for this study are the quality cost data reported by Westinghouse divisions in response to a Corporate requirement, and financial statements of these same divisions, (coded in this paper).

SEARCH FOR A MEASURE

Initially our attention was put on total quality costs (TQC), with the expectation that the best performing divisions would have the lowest TQC. However, a ranking of divisions by TQC did not agree with rankings based on other measures - such as the division's reputation for quality, or the findings of Corporate Quality Program Audits. A better measure was found when attention was limited to failure (F) costs alone. Divisions with low failure costs were also found to have better reputation for quality performance.

Figure 1 illustrates the performance of 3 similar divisions between 1975 and 1977. All three divisions introduced quality program improvements during 1975 which contributed to lower failure costs in 1976 and 1977 - lower in dollars and lower as a percentage of Value-Added Sales.

Failure cost relative to value-added sales (F% VAS) was found to be a better indicator of quality performance trends than the more common measure of F% total sales billed, since V.A.S. is a better measure of opportunity for failure costs to occur. (Value-Added Sales is the difference between gross sales billed and the cost of purchased material or services.)

Figure 1 shows not only that these divisions achieved a reduction in F% VAS, but also (as predicted by the PIMS study) that the profit performance of these divisions improved when failure costs were reduced.

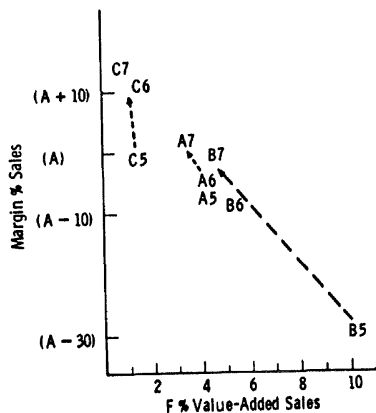


FIGURE 1

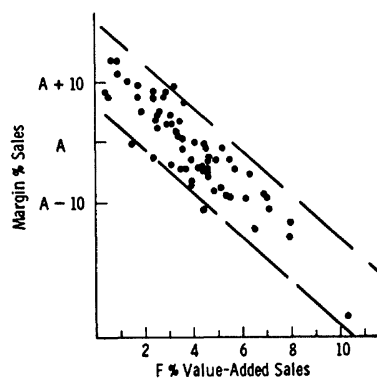


FIGURE 2

Figure 2 shows the relationship when data for other divisions is added to the nine data points of Figure 1. The letter "A" on the vertical scale represents what was defined to be an acceptable level of profit performance. The data show good linear correlation ($r = -0.90$) between profit margin (M% sales) and failure costs (F% VAS).

From this data the least-squares regression line was found to be:

$$M = (A+13) - 3.6 F_{vas}$$

The observation that failure costs and profit performance are highly correlated does not in itself prove that either is a direct cause of the other. External factors such as an industry-wide change in demand for the product can cause both profit margin and

F% VAS in a particular division to shift -- even though no change may have occurred in quality performance itself.

Whether or not a cause-and-effect relationship is present, the correlation of margin to failure costs can be highly useful -- for example, to test the credibility of reported failure cost data. For the 64 data points shown in Figure 2, the difference between actual profit margin and the margin predicted by the regression mode has a standard deviation of 3.5 percentage points. The two parallel lines in this figure lie two standard deviations (seven points of profit margin) above and below the least-squares regression line, and therefore represent upper and lower boundaries of a 95% confidence band for margin as a function of failure cost.

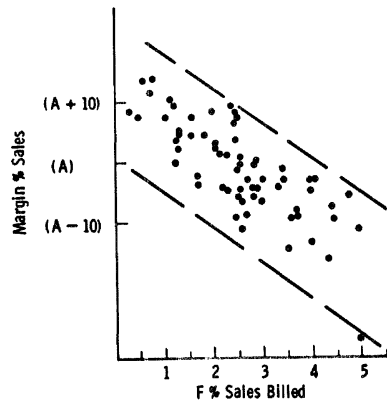
When data points are found to lie outside the appropriate confidence band, they should be investigated. The few exceptions observed were investigated, and in nearly every case this investigation revealed errors in the reporting of failure cost data -- for example, use of estimates or accrual rates rather than actual failure costs.

As mentioned earlier, some of the correlation between margin and failure costs may be the result of both factors responding simultaneously to a third variable. Nonetheless, there are also indications that a strong cause-and-effect relationship is present, and that a sustained program for reducing failure costs can make a major contribution to improved profit performance.

THE MULTIPLIER EFFECT

Figure 3 helps to demonstrate the profit impact of a one-dollar change in failure cost. (The same measurement base is used for both variables.) The least squares regression line for 64 data points becomes

$$M = (A + 12.6) - 5.45 (F\% \text{ Sales}).$$



Although the linear correlation for M:F% sales ($r = -0.79$) is not quite as good as for M:F% VAS, use of the same measurement base (sales billed) reveals the existence of a strong "multiplier effect". The slope of 5.45 means that profit margin (before taxes) improves an average of \$5.45 for every \$1.00 reduction in reported failure costs.

FIGURE 3

Most managers are aware that some costs of quality failure are not easily identified as failure costs, but that they affect profit nonetheless:

- o in-process quality failures may cause parts shortages which create production downtime at subsequent operations;
- o some in-section rework is absorbed in productivity and reported as a labor variance;
- o chronic rework or excessive "shrinkage" may necessitate scheduling of overtime or purchase of additional production facilities;

- o completed product which fails in final test may result in increased work-in-process inventory and reduced billings for the month;
- o product failures in the field can, at least in the long run, contribute to reduced market share or poor price realization. They may also contribute to past-due or uncollectible receivables.

Although most managers recognize failure effects such as these (sometimes called "symptoms of failure disease"), it has not been common practice to quantify the expected benefit in these areas when attempting to justify capital expenditures for quality improvement. Some of the observed slope of 5.45 may be only coincidental, but our experience indicates that a multiplier effect of at least three or four is directly related to such hidden effects of quality failure.

FINDING OPTIMUM "BALANCE"

This multiplier effect of failure costs on profits also explains why minimum TQC is hardly ever optimum. Reported quality costs are typically at their lowest when the voluntary costs of quality (prevention plus appraisal) are about equal to the reported failure costs -- or 40% to 60% of TQC, as shown by the solid lines in Figure 4. If, however, the "true" cost of failure is found to be more nearly four times the reported costs, the point of true minimum cost would move further to the right, as shown by the broken lines of Figure 4.

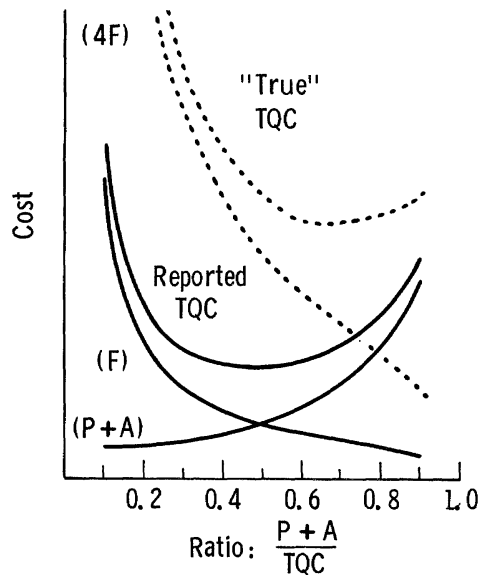


FIGURE 4

Our data tend to confirm this. Reported TQC is at a minimum when prevention plus appraisal cost (P+A) constitute about half of the reported total quality cost (TQC), but profits continue to improve until (P+A) contributes 70% to 80% of the reported TQC.

EVALUATING PROGRAM EFFECTIVENESS

Since a particular level of profit margin (A) was defined as "acceptable", and since our data confirms the PIMS finding that divisions with better quality performance also earn more profits, we used this relationship to define an acceptable level of failure costs. The level of failure costs at which the M:F regression line crosses $M = A \% \text{ sales}$ is described as F_{par} , and the level of failure costs at which

the regression line crosses $M = (A-8)$ % sales is defined as F_{tol} .

For the divisions included in Figure 2 data these points were found to be $F_{par} = 3.6\%$ VAS and $F_{tol} = 5.8\%$ VAS (See Figure 5). Divisions whose reported failure costs are less than or equal to F_{par} are considered "green" -- shown as zone "G" in Figure 5.

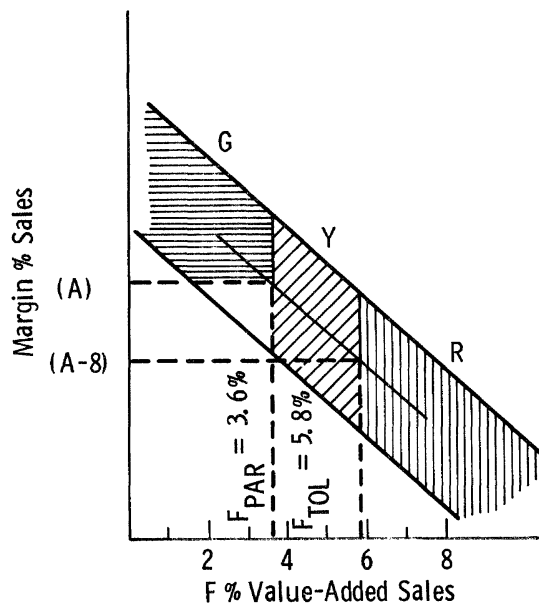


FIGURE 5

On the other hand, when reported failure costs exceed F_{tol} the status is considered "Red", and the division is suspected to have some form of "failure disease". We contact these "Red" divisions to determine which specific symptoms of failure disease might be present (low productivity, missed billings, loss of market share, etc.) and begin to work with them in establishing a program for improvement.

As you might suspect, when reported failure costs lie between F_{par} and F_{tol} the performance is considered "yellow". If left alone, yellow will usually change to red.

FAMILY OF PROFILE TYPES

Finally, we should say a word about the selection of divisions included in Figure 2. Not all Westinghouse divisions fit this profile type, although it is the most common.

Some divisions continue to report margin and failure costs which fall above and to the right of the data plotted in Figure 2. Typically these divisions also tend to be in higher risk divisions, with higher technology requirements for their products or services. Such divisions fit the profile types III or IV shown in Figure 6.

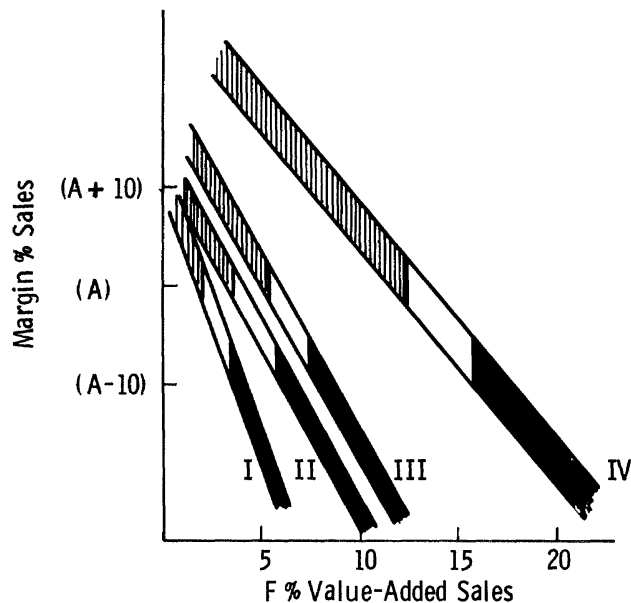


FIGURE 6

Other divisions report margin and failure costs which fall below and to the left of the Type II profile divisions. In many cases, these divisions are engaged in a more mature business, with reduced technological requirements. However, the steeper slope of these Type I divisions also implies that fewer of the real costs related to failure are identified and reported. (So long as the reporting is consistent from month-to-month, and the portion of failure costs which is identified and reported is a valid indicator of performance trends, this "under-reporting" need not cause concern.)

Performance standards will of course differ for the various profile types. At present, we are using the same level of profit margin ($M = A \% \text{ Sales}$) to define F_{par} . As shown in Figure 6, our observed values of F_{par} are as follows:

Type I:	2.0 % VAS
Type II:	3.6 % VAS
Type III:	5.3 % VAS
Type IV:	12.4 % VAS

As more years of margin and failure cost data are collected, it will become less important to group divisions by profile type.

(SUMMARY)

The observed correlation between failure costs and profit performance has many uses as a tool of quality management. A particular division which shows no margin-to-failure correlation is likely to be reporting failure costs which are not responsive indicators of actual performance trends. A division whose data does fit a profile-type has most need for quality program improvement if its status is "yellow" or "red".

Perhaps of greatest interest is the slope of the M:F regression line; every dollar of improvement in reported failure costs is likely to result in several dollars improvement in profits. In many instances, this kind of payoff is more fruitful than the more traditional efforts to reduce direct product labor or material costs.

In a nutshell, Shewhart (4) said it first and best: "... when assignable causes of variation in quality have been eliminated ... the product may then be considered to be controlled ... this state of control appears to be, in general, a kind of limit to which we may expect to go economically in finding and removing causes of variability ..." (emphasis added.)

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LCS 630:10:000

GROUP PROCESSES IN PROBLEM SOLVING

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Successful problem solving requires the use of strategies, techniques and innovative ideas. When working in groups, the problems of the interaction among the group members also becomes important. Frequently, due to inexperience or a lack of understanding about group processes, interaction among group members reduces the effectiveness of the group in solving the problems.

The purpose of this paper is to describe some concepts and techniques which are useful when task forces and committees are solving problems. The specific items to be discussed are Cog's Ladder, a model that describes the steps which a group progresses through as it matures; and nominal group techniques (NGT) which can be used during the problem solving process to reduce the impact of problems related to interaction within the group.

Cog's Ladder

Charrier⁽¹⁾ has described a model of group growth which he designated as Cog's Ladder. This model describes the phases through which a group passes as it matures to become an effective team. The model is useful in relating observations about a group as problem solving proceeds.

Cog's Ladder is a five stage model. The stages have been designated as (1) polite, (2) why are we here?, (3) bid for power, (4) cooperative, and (5) esprit.

In the polite stage the group members are becoming acquainted. Controversy is avoided, ideas are simple, small talk is the usual course of events. This phase is necessary for people to establish some common ground and to begin to feel comfortable with each other. It occurs every time the group convenes, even after a number of sessions working as a team.

The second stage, "why are we here?," is used to establish the goals and objectives to be achieved. In a problem solving situation, this is when the problem is defined and the purpose to be achieved is established. Participation is very active on the part of all members and disagreement can occur. In this phase it is important to build some measure of commitment to the purpose to be achieved.

The third stage, bid for power, is characterized by competition. The purpose of the group has been determined and active problem solving has started. It is typical of group members in this phase to propose and lobby for their favorite solutions. Group members tend to talk rather than listen and unconventional solutions will fall flat. If a group member does not really agree with the purpose to be achieved, this disagreement will reappear in this stage. The leader of the group can lose power and leadership at this point or he may dominate the group himself.

When a group moves from the third stage to the fourth or cooperative stage an attitude change occurs. Group members actively listen to each other, and are willing to change based on what they hear. Creative suggestions are now accepted and discussed. Group commitment to the purpose is high as is tolerance of individual differences.

In the esprit stage, cooperation and creativity reach a synergistic level. Each member can express his individuality in problem solving. Members of the group can disagree while still respecting each other's views.

Moving from stage one to stage two requires that people must accept the possibility of working on a threatening problem. This may occur if the problem is related to a system in which the team member has a vested interest. In moving from stage two to stage three, a member may be required to commit himself to working at a purpose level which he does not agree with. This can occur in problem solving when some team members insist on solving only the immediate problem while others believe that considering a broader problem may yield a better solution. To grow from stage three to stage four each individual must give up the comfort of defending his own views and risk the possibility of being wrong. To grow from stage four to stage five demands mutual trust among the team members.

Problem solving can occur in stages three, four, and five. However, the quality of the solution and the effectiveness of the group is likely to be better if the group is operating in stages four or five. One of the jobs of the leader is to move the group to stage four as rapidly as possible. How rapidly a group moves through the stages is affected by the skill of the leader and the techniques used.

Groups in problem solving usually operate in an interactive mode. Although the interactive mode is useful, it has certain characteristics which tend to keep

the group in phase three. Van de Ven and Delbecq⁽²⁾ have commented on those characteristics of interacting groups which inhibit problem solving. Those which resemble phase three characteristics are (1) self-weighting effect (participation in the group only to the extent that the individual feels equally competent with others), (2) covert judgements which are not expressed as overt criticisms, (3) the tendency of low status individuals to go along with the opinion of high status participants, (4) group pressures for conformity and the implied threat of sanctions, and (5) the influence of dominant personality types.

Other inhibiting influences are (1) falling into a rut and following a single train of thought, (2) mixing solution generation and analysis, and (3) the amount of effort required to maintain the group interaction.

Nominal Group Techniques

Another group process which can be used in problem solving is the nominal group. A nominal group is a group of people working together on the same problem but without verbal interaction.

The nominal group technique (NGT) as developed by Delbecq and Van de Ven is a combination of nominal group processes and interactive processes. Using NGT, solutions to a problem are generated in the nominal group mode. The participants work in silence and record their ideas on paper. When this phase is complete, the ideas are solicited from the participants in a round robin fashion and recorded on a flip chart pad. When all ideas have been recorded, they are discussed for clarification in an interactive mode. If a judgement or group decision is required, this is achieved by using a nominal process to record the first judgement of each participant. These are then listed and discussed interactively. A final group judgement is obtained in the nominal mode. Specific instructions for using NGT have

been described by Delbecq, Van de Ven, and Gustafson⁽³⁾.

There are several aspects of NGT which eliminate problems that can occur in group problem solving. Solution generation, clarification and evaluation are separated. The problem solving strategy used also can facilitate this separation⁽⁴⁾.

Working in a nominal group forces each person to participate in the generation of ideas. By soliciting one idea in turn from each person, each is given the opportunity to participate and present ideas. During clarification the discussion is directed so as to focus on understanding the idea. Usually, this can be done by resorting to the rules of NGT. By making the evaluation and selection of solutions in a nominal mode, it is possible to eliminate pressure from higher status individuals. If the final step is done in a manner which eliminates the identity of final individual decisions, all pressure is removed.

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COMMUNICATION AND COOPERATION

Whether to use a nominal or interacting mode is a matter of judgement. The decision will be affected by the size of the group, the leader's knowledge of the group members, his observations on their ability to interact and the task to be accomplished. The nominal mode is useful for exploring the facets of a problem, generating solutions and entering individual judgements. The interacting mode is useful when clarifying or analyzing possible solutions. Large groups can be split into smaller groups as described in (3).

Teams consisting of technical people will tend to move to stage four. However, there usually are some members who have difficulty progressing past stage three. In our classes in problem solving we have observed that most teams move rather rapidly to stage four. On a few occasions a team has actually moved to stage five on their last problem. These teams recognized that they were in stage five and the quality and quantity of their work was considerably above that produced by other teams on the same problem.

Knowledge of Cog's Ladder and NGT has been useful to our problem solving teams. People recognize situations in terms of the model and can understand what is happening. As people become experienced in using NGT, they recognize situations where it can be used and apply it.

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LCS 320:00:000

DATA MANAGEMENT - AN APPROACH TO QUALITY CONTROL

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As a complex instrument business begins to rapidly expand, it becomes extremely difficult and ineffective to maintain Quality functions by mere manual techniques. The continual evolvement of a new and sophisticated diagnostic instrument composed of many discrete subassemblies poses configuration control problems that can readily become unmanageable. In order to cope with such a rapidly expanding instrument business in a regulated industry, a computerized approach to the analysis of Quality data was found to be essential.

This paper describes a Quality Control Data Management System that was designed, developed and implemented to provide a means of accumulating, storing, tabulating and reporting of Quality parameters such as configuration control, subassembly location, failure rates, failure modes and historical data of instruments and subassemblies.

The tracking system provides a comprehensive defect and applications history of each subassembly from its time of manufacture through test, acceptance, depot storage and installation in instruments throughout the world.

Considerations and relative cost trade-offs are discussed in the selection of the type of format and computer system selected (i.e., timesharing, dedicated or central processor). Some actual examples are given to demonstrate the effectiveness of computerized data reporting in identifying and relating otherwise obscure or undetectable Quality problems.

LCS 346:70:428

THE p CONTROL CHART UNDER INSPECTION ERROR

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ABSTRACT

One true test of management is the degree to which it is committed to producing quality products and services. Although quality cannot be "inspected into" a product, the inspection task is crucial in helping identify when an excessive number of defectives is being produced.

The p chart is a classic, well accepted control chart used to determine whether or not a state of statistical control exists. Basically, when the observed fraction defective falls outside control limits, an assignable cause is sought. Of course, it is always implicitly assumed that inspection results are perfect.

Many independent researchers and practitioners have conclusively shown that inspectors do make mistakes, classifying bad items as good and vice versa. Further, inspection error rates of as high as 40% are not uncommon.

This paper mathematically and graphically examines the effects of inspection error on the p chart. The point of view where control limits are based upon a target value, and the point of view where control limits are based upon error-prone data, are both considered. Further, a compensating p chart is offered to help provide an OC curve more near to that desired. Also, the OC curve of a p chart under variable error rates is explained and illustrated.

The results of this paper should be of interest to concerned managers who desire to turn out a quality product but who may have never considered the possibility that their inspection process is imperfect, let alone the ill effects of inspection error. The paper closes with a brief discussion of some of the causes and cures of inspection error, including a large number of references. All results are illustrated by example.

INTRODUCTION

Control charts are an important part of the body of literature known as "statistical quality control." The "p" chart, in particular, is a well known attributes control chart which is easily used, and for which data are often readily available. The accuracy of the inspection process in which items are classed as either good or defective is fundamental to the use of a p chart. Although there is almost always implicit faith in the inspection process, inspection results which cannot be trusted cast doubt upon the use of a p chart to indicate the state of process control.

The entire body of literature on the p chart, including numerous texts which have excellent coverage, assumes inspection to be free of error. Conclusive evidence exists, however, to show that attributes inspection tasks are far from error-free [2, 5, 6, 7, 9, 10, 11, 13, 14, 16, 17, 19]. Even under ideal inspection conditions, error rates exceeding 25% are not uncommon [2, 5, 6, 7, 9, 16]. As a result, some organizations are taking a hard look at the effectiveness of their inspection procedures and equipment; however, inspection error will certainly not be eliminated.

The effects of inspection error have been considered by several authors on various aspects of attributes acceptance sampling plans [1, 2, 3, 4, 8, 12, 13, 14, 18, 20, 21, 22, 23, 24, 25]. In these papers, performance measures such as probability of acceptance, average outgoing quality, average total inspection, total cost per lot, and others have been extensively treated. A broad-based introductory paper to attributes acceptance sampling under inspection error is given by Collins, et al [4]. Even variables acceptance sampling under measurement error is currently generating much interest and a growing body of literature.

Control charts under error, to the contrary, have received almost no attention, with the exception of a recent paper by Abraham [21] covering \bar{X} , R, and cusum variables charts under the assumption of imperfect inspection. There has been no similar paper published for the p chart, or for any attributes control chart.

The purpose of this paper is, therefore, to determine and illustrate the effects of inspection error on the operating characteristic curve of the p chart under two different (and realistic) points of view. In addition, a procedure for determining control limits which partially compensate for inspection error will be developed and illustrated.

NOTATION

Following is the notation to be used throughout this paper. Summarizing it here will facilitate further development.

- n = size of sample taken or considered for p chart purposes
- x = actual number of defectives in the sample
- p = true process fraction defective
- CL_p = center line of the p chart based upon the actual or target fraction defective
- UCL_p = upper control limit of the p chart based upon the actual or target fraction defective
- LCL_p = lower control limit of the p chart based upon the actual or target fraction defective
- x_L = largest number of actual defectives observed in a sample of size n which yields a sample fraction defective within control limits
- x_S = smallest number of actual defectives observed in a sample of size n which yields a sample fraction defective within control limits
- P_a = probability that the actual sample fraction defective $\frac{x}{n}$ falls within control limits
- e_1 = probability that a good item will be erroneously classified as defective
- e_2 = probability that a defective item will be erroneously classified as good
- y_e = the number of apparent defectives in the sample. Note that some of these may have been incorrectly classified.
- p_e = apparent process fraction defective
- P_1 = a point of view in which the p chart is based upon a target value
- y_{eL1} = largest number of apparent defectives observed in a sample of size n which yields a sample apparent fraction defective within control limits based upon the actual or target fraction defective
- y_{eS1} = smallest number of apparent defectives observed in a sample of size n which yields a sample apparent fraction defective within control limits based upon the actual or target fraction defective
- P_{ae1} = probability that the apparent fraction defective $\frac{y_e}{n}$ falls within control limits based on the actual or target fraction defective
- P_2 = a point of view in which the p chart is based upon data
- CL_{p_e} = center line of the p chart based upon the mean apparent fraction defective
- UCL_{p_e} = upper control limit of the p chart based upon the mean apparent fraction defective
- LCL_{p_e} = lower control limit of the p chart based upon the mean apparent fraction defective
- y_{eL2} = largest number of apparent defectives observed in a sample of size n which yields a sample apparent fraction defective within control limits based upon the mean apparent fraction defective
- y_{eS2} = smallest number of apparent defectives observed in a sample of size n which yields a sample apparent fraction defective within control limits based upon the mean apparent fraction defective

- P_{ae2} = probability that the apparent fraction defective $\frac{y_e}{n}$ falls within control limits based upon the mean apparent fraction defective
- CL_{p_c} = center line of the inspection error compensating p chart
- UCL_{p_c} = upper control limit of the inspection error compensating p chart
- LCL_{p_c} = lower control limit of the inspection error compensating p chart
- y_{e2c} = largest number of apparent defectives observed in a sample of size n which yields a sample apparent fraction defective within the compensating control limits
- y_{esc} = smallest number of apparent defectives observed in a sample of size n which yields a sample apparent fraction defective within the compensating control limits
- P_{aec} = probability that the apparent fraction defective $\frac{y_e}{n}$ falls within the compensating control limits

DEVELOPMENT - NO INSPECTION ERROR

The standard Shewhart p control chart has a center line, an upper control limit, and a lower control limit. A statistic representing the sample fraction defective and based upon the data collected is compared against the control limits. If the statistic falls within the limits, the user continues to believe that a state of statistical control exists. If outside the limits, the user concludes that excessive variability exists and that an assignable cause must be affecting the process.

In this paper, two points of view will be considered. They are as follows:

- P1. The p chart is established based upon a desired fraction defective. In this case, no data are used in setting up the chart. Rather, the target value, p, is stated as the center line and control limits are developed accordingly.
- P2. The p chart is established based upon data. In this case, the center line of the chart will be the average fraction defective over an appropriate number of observed samples. Control limits will also be determined based upon the average fraction defective.

If "p" is considered the target value in P1 or the average sample fraction defective in P2, the p chart may be characterized as follows:

$$\text{Center Line} = CL_p = p \quad (1)$$

$$\text{Upper Control Limit} = UCL_p = p + 3 \sqrt{\frac{p(1-p)}{n}} \quad (2)$$

$$\text{Lower Control Limit} = LCL_p = p - 3 \sqrt{\frac{p(1-p)}{n}} \quad (3)$$

When a sample of size n is taken, the sample fraction defective given by the statistic $\frac{x}{n}$ is compared to the control limits. The largest and smallest values of x for which an in-control state is indicated are,

$$x_L = [n \cdot UCL_p]^- \quad (4)$$

$$x_S = [n \cdot LCL_p]^+ \quad (5)$$

where $[]^-$ and $[]^+$ indicate round-down and round-up operations, respectively, to the nearest integer. The Operating Characteristic (OC) curve illustrates the probability P_a that a sample fraction defective $\frac{x}{n}$ will fall within control limits as a function of the true process fraction defective p . That is,

$$P_a = \sum_{x=\max(0, x_S)}^{x_L} \binom{n}{x} p^x (1-p)^{n-x} \quad 0 \leq p \leq 1 \quad (6)$$

Example 1: Consider a process either targeted (P1) or currently operating in control (P2) at process fraction defective $p = .10$. Samples of size $n = 100$ are taken periodically. It is desired to describe the control chart, and illustrate its OC curve.

The control chart is characterized as follows:

$$CL_p = .10$$

$$UCL_p = .10 + 3 \sqrt{\frac{.10(.90)}{100}} = .19$$

$$LCL_p = .10 - 3 \sqrt{\frac{.10(.90)}{100}} = .01$$

The values of x_L and x_S are

$$x_L = [100 \cdot .19]^- = 19$$

$$x_S = [100 \cdot .01]^+ = 1$$

The OC curve is then expressed mathematically as

$$P_a = \sum_{x=1}^{19} \binom{100}{x} p^x (1-p)^{100-x} \quad 0 \leq p \leq 1$$

This OC curve is illustrated in Figure 1 for a range of p from .005 to .300. Note that the OC curve increases very rapidly as small values of p increase, levels off at approximately 1.0 in a wide neighborhood about $p = .10$, and decreases very rapidly as p continues to increase.

— See Figure 1 —

DEVELOPMENT - INSPECTION ERROR

The Nature of Inspection Error

Two types of errors are possible in attribute sampling. An item which is good may be classified as defective (type I error), or a defective item may be classified as good (type II error).

Let

E_1 = the event that a good item is classified as a defective,

E_2 = the event that a defective item is classified good,

A = the event that an item is defective,

and

B = the event that an item is classified as a defective.

Then,

$$P(B) = P(A)P(\bar{E}_2) + P(\bar{A})P(E_1). \quad (7)$$

By defining the quantities

$p = P(A)$, true fraction defective,

$p_e = P(B)$, apparent fraction defective,

$e_1 = P(E_1)$, the probability the E_1 occurs,

and

$e_2 = P(E_2)$, the probability that E_2 occurs,

the expression for the apparent fraction defective may be more meaningfully expressed as [1, 2, 3, 4, 12, 13, 14, 15, 18, 20, 22, 23, 24, 25].

$$p_e = p(1-e_2) + (1-p)e_1 \quad (8)$$

The use of this apparent fraction defective as observed by the inspector depends upon the point of view taken. Both P_1 and P_2 will be considered in the following sections.

P_1 - p As a Target Value

If p is treated as a target value, the center line and control limits for the p chart will be exactly as given in Equations (1), (2), and (3). Now, however, the

statistic of interest is the sample apparent fraction defective $\frac{y_e}{n}$ where y_e is the number of apparent defectives observed by the inspector. The largest and smallest values of y_e for which an in-control state is indicated are

$$y_{e1} = [n \cdot UCL_p]^- \quad (9)$$

$$y_{e2} = [n \cdot LCL_p]^+ \quad (10)$$

The OC curve under inspection error is now given by

$$P_{ae1} = \sum_{y_e = \max(0, y_{e1})}^{y_{e2}} \binom{n}{y_e} p_e^{y_e} (1-p_e)^{n-y_e} \quad 0 \leq p_e \leq 1 \quad (11)$$

Clearly, although the control chart remains identical to the error-free case, inspection error will distort the OC curve of the p chart.

Example 2: To illustrate the effect of inspection error let us reconsider Example 1 in which the control chart is based on $p = .10$ and the control limits are $UCL_p = .19$, $LCL_p = .01$. Let the inspection process be confounded by error (e_1, e_2). In order to be able to isolate the effect of e_1 and e_2 singly as well as in combination, perfect inspection plus three error pairs are considered: (e_1, e_2) = (.00, .00); (.03, .00); (.00, .30); (.03, .30). The OC curve under inspection error is given by

$$P_{ae1} = \sum_{y_e=1}^{19} \binom{100}{y_e} p_e^{y_e} (1-p_e)^{100-y_e} \quad 0 \leq p_e \leq 1$$

Figure 2 illustrates the OC curve under each error pair considered. It is easily seen that realistic quantities of error have a dramatic effect on the OC curve.

— See Figure 2 —

From Example 2 it is obvious that an e_1 error increases the value of P_{ae1} for low process fractions defective, and decreases the value of P_{ae1} at high process fractions defective. Recall that an e_1 error is the erroneous classification of a good item as defective. Therefore, it is reasonable that errors are made, when the process fraction defective is low, which increase the likelihood that the sample statistic $\frac{y_e}{n}$ falls above the lower control limit, causing P_{ae1} to increase. Similar reasoning explains the propensity for an e_1 error to cause the sample statistic to fall above the upper control limit, causing P_{ae1} to decrease.

It is also obvious that an e_2 error decreases the value of P_{ae1} for low fractions defective, and increases the value of P_{ae1} at high process fractions defective. Recall that an e_2 error is the erroneous classification of a defective item as good. Therefore, it is reasonable that errors are made, when the process fraction defective is low, which increase the likelihood that the sample statistic $\frac{y_e}{n}$ falls below the lower control limit, causing P_{ae1} to decrease. Similar reasoning explains the propensity for an e_2 error to cause the sample statistic to fall below the upper control limit, causing P_{ae1} to increase.

When both the e_1 and e_2 errors are operative together, the e_1 error has more influence on the OC curve for low p , while the e_2 error dominates the OC curve for high p . The reason is that when the actual process fraction defective is quite low, there is little opportunity for the realization of an e_2 error. However, as p increases, the e_2 error becomes increasingly dominant. These results are consistent with those found for attributes acceptance sampling OC curves [4, 12, 22, 23, 24].

If the control chart is based upon data collected under inspection error, its center line and control limits will be modified from Equations (1), (2), and (3). Specifically, the center line will now be the average of a large number (often about 30) of values of the sample statistic $\frac{y_e}{n}$. For simplicity, the notation p_e is used for this value since it is the mean of this sample statistic. Basing the control chart upon this value results in

$$\text{Center Line} = CL_{p_e} = p_e \quad (12)$$

$$\text{Upper Control Limit} = UCL_{p_e} = p_e + 3 \sqrt{\frac{p_e(1-p_e)}{n}} \quad (13)$$

$$\text{Lower Control Limit} = LCL_{p_e} = p_e - 3 \sqrt{\frac{p_e(1-p_e)}{n}} \quad (14)$$

Just as in P1, the statistic of interest is the sample apparent fraction defective $\frac{y_e}{n}$. The largest and smallest values of y_e for which an in-control state is indicated will now be

$$y_{eL2} = \left[n \cdot UCL_{p_e} \right]^- \quad (15)$$

$$y_{eS2} = \left[n \cdot LCL_{p_e} \right]^+ \quad (16)$$

The OC curve in this case is given by

$$P_{ac2} = \sum_{y_e = \max(0, y_{eS2})}^{y_{eL2}} \binom{n}{y_e} p_e^{y_e} (1-p_e)^{n-y_e} \quad 0 \leq p_e \leq 1 \quad (17)$$

Now the control limits as well as the sample statistic are based upon error-prone inspection; however, it is unclear from Equation (17) what effect this will have on the OC curve.

Example 3: Again let us consider Example 1, and assume that the p chart is now based upon data observed from an error prone inspection process operating at an actual fraction defective $p = .10$. The same four fractions defective considered in Example 2 will be used: $(e_1, e_2) = (.00, .00); (.03, .00); (.00, .30); (.03, .30)$. The center line and control limits will change as a function of each error pair considered.

To illustrate the calculations underlying the p chart in this case let $(e_1, e_2) = (.03, .30)$.

$$\text{Center Line} = CL_{p_e} = p_e = p(1-e_2) + (1-p)e_1 = (.10)(1-.30) + (1-.10)(.03) = .097$$

$$\text{Upper Control Limit} = UCL_{p_e} = .097 + 3 \sqrt{\frac{.097(1-.097)}{100}} = .18579$$

$$\text{Lower Control Limit} = LCL_{p_e} = .097 - 3 \sqrt{\frac{.097(1-.097)}{100}} = .00821$$

$$\begin{aligned} \text{The values of } y_{eL2} \text{ and } y_{eS2} \text{ are } y_{eL2} &= \left[100 \cdot .18579 \right]^- = 18 \\ y_{eS2} &= \left[100 \cdot .00821 \right]^+ = 1 \end{aligned}$$

The OC curve under this error pair would be given by

$$P_{ac2} = \sum_{y_e=1}^{18} \binom{100}{y_e} p_e^{y_e} (1-p_e)^{100-y_e} \quad 0 \leq p_e \leq 1$$

Figure 3 illustrates the OC curve under each error pair considered. Table I presents the center line and control limit values relevant to this example.

— See Figure 3 —

Table I. Center Line and Control Limit Values
for Example 3.

(e_1, e_2)	CL_{p_e}	UCL_{p_e}	LCL_{p_e}
(.00, .00)	.10000	.19000	.01000
(.03, .00)	.12700	.22689	.02711
(.00, .30)	.07000	.14654	.00000
(.03, .30)	.09700	.18579	.00821

In Example 3, each of the OC curves under inspection error deviates from the desired OC curve marked by $(e_1, e_2) = (.00, .00)$. For high values of p these deviations are not nearly as severe as those from Example 2 illustrated in Figure 2. This is because the control limits used in Example 3 are actually based upon the error prone data, and partially compensate for the variability of the sample apparent fraction defective. For low values of p , the deviations from the desired OC curve are somewhat extreme. This is largely due to the particular example illustrated, having a lower control limit so near .00.

COMPENSATING p CHART

A center line and control limits may be determined for the p chart which, to a large extent, compensate for inspection error and provide an OC curve closer to that desired. The basic approach to be presented is applicable to both P1 and P2.

First the center line and control limits are determined using Equations (1), (2), and (3). This is easily done when point of view P1 is employed, based upon the target value or actual fraction defective p . However, approach P2 relies upon the apparent fraction defective p_e . Thus, the value of p to use in Equations (1), (2), and (3) may be found by solving Equation (8) for p :

$$p = \frac{p_e - e_1}{1 - e_1 - e_2} \quad (17)$$

Once the center line CL_p and control limits UCL_p and LCL_p have been determined, the compensating center line CL_{p_c} and control limits UCL_{p_c} and LCL_{p_c} are calculated as follows:

$$\text{Center Line} = CL_{p_c} = CL_p(1 - e_2) + (1 - CL_p) e_1 \quad (18)$$

$$\text{Upper Control Limit} = UCL_{p_c} = UCL_p(1 - e_2) + (1 - UCL_p) e_1 \quad (19)$$

$$\text{Lower Control Limit} = LCL_{p_c} = LCL_p(1 - e_2) + (1 - LCL_p) e_1 \quad (20)$$

Note that the compensating control chart simply reflects taking the error-free center line and control limit fractions defective, and using Equation (8) to convert them to error-prone equivalents.

The largest and smallest values of y_e for which an in-control state is indicated are

$$y_{eLc} = \left[n \cdot UCL_{p_c} \right]^- \quad (21)$$

$$y_{esc} = \left[n \cdot LCL_{p_c} \right]^+ \quad (22)$$

The OC curve using the compensating control chart under inspection error is now given by

$$p_{aec} = \sum_{y_e = \max(0, y_{esc})}^{y_{eLc}} \binom{n}{y_e} p_e^{y_e} (1 - p_e)^{n - y_e} \quad 0 \leq p_e \leq 1 \quad (23)$$

Example 4: Continuing with the same basic example, let us determine compensating control charts and OC curves for each error pair of interest. For illustration purposes, only the control chart for $(e_1, e_2) = (.03, .30)$ will be considered. It is already known from Example 1 that $CL_p = .10$, $UCL_p = .19$, and $LCL_p = .01$. Using Equations (18), (19), and (20):

$$CL_{p_c} = .10(1-.30) + (1-.10) .03 = .09700$$

$$UCL_{p_c} = .19(1-.30) + (1-.19) .03 = .15730$$

$$LCL_{p_c} = .01(1-.30) + (1-.01) .03 = .03670$$

The values of $y_{e_{zc}}$ and $y_{e_{sc}}$ are

$$y_{e_{zc}} = \left[100 \cdot .15730 \right]^- = 15$$

$$y_{e_{sc}} = \left[100 \cdot .03670 \right]^+ = 4$$

The OC curve under this error pair would be given by

$$p_{aec} = \sum_{y_e=4}^{15} \binom{100}{y_c} p_e^{y_e} (1-p_e)^{100-y_e} \quad 0 \leq p_e \leq 1$$

Figure 4 illustrates the OC curve under each error pair considered. Table II presents the compensating center line and control limit values relevant to this example.

— See Figure 4 —

Table II. Compensating Center Line and Control Limit Values for Example 4

(e_1, e_2)	CL_{p_c}	UCL_{p_c}	LCL_{p_c}
(.00, .00)	.10000	.19000	.01000
(.03, .00)	.12700	.21430	.03970
(.00, .30)	.07000	.13300	.00700
(.03, .30)	.09700	.15730	.03670

In Example 4, the compensating control charts for each error pair provide OC curves which are quite close to the desired curve at $(e_1, e_2) = (.00, .00)$. In fact, the method presented for designing compensating control charts provides exactly the desired OC curve as n increases without bound. Practically speaking, this means that the compensating control chart provides better results for larger sample sizes.

NON-CONSTANT INSPECTION ERROR

Biegel [2] proposed that for some inspection processes, inspection error is a linear function of the actual fraction defective p . This is in contrast to the constant error rates used to this point. Specifically, he assumes Types 1 and 2 error are, respectively, given by

$$e_1(p) = 1 - (a_1 + b_1 p) \quad (24)$$

and

$$e_2(p) = 1 - (a_2 + b_2 p). \quad (25)$$

With the exception of these changes, the equations relevant to points of view P1 and P2 remain the same.

Example 5: As a matter of interest, consider the same basic problem faced in Example 2, but now allowing error to vary linearly with the actual fraction defective. Using results very close to those of Biegel [2] based on data

$$e_1(p) = 1 - (.1518p) \quad \text{and} \quad e_2(p) = 1 - (.6884 + .4190p)$$

Using a p chart having $CL_p = .10$, $UCL_p = .19$, and $LCL_p = .01$, the resulting OC curve is contrasted with the error-free OC curve as shown in Figure 5. Table III lists the error pairs and the apparent fraction defective p_e for a few values of the actual fraction defective p .

-- See Figure 5 --

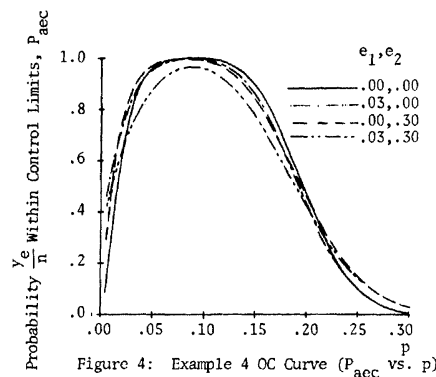
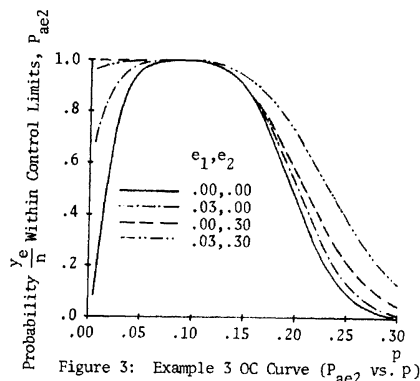
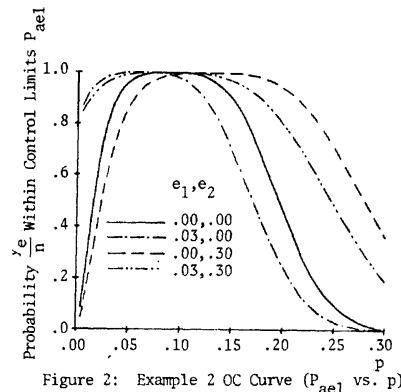
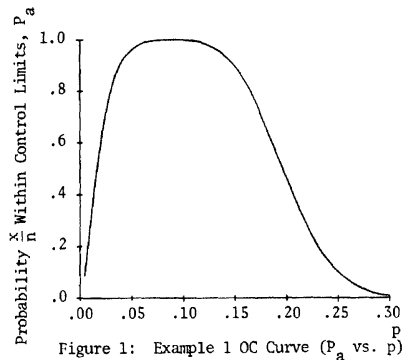
Table III. Selected Values of p , $e_1(p)$, $e_2(p)$, and p_e Used in Example 5

p	$e_1(p)$	$e_2(p)$	p_e
.05	.00759	.29065	.04268
.10	.01518	.26970	.08669
.15	.02277	.24875	.13204
.20	.03036	.22780	.17873
.25	.03795	.20685	.22675

SUMMARY AND CONCLUSIONS

This paper has shown that inspection error rates which are not unrealistic in industry seriously affect the OC curve of a p control chart. It may come as a surprise to many that inspection error exists at the levels illustrated, and that it can distort the OC curve so badly. To those who have been concerned with inspection accuracy problems, the results illustrated in this paper should come as no real surprise.

One of the features of this paper is a method of developing a control chart which partially compensates for inspection error. However, the author recommends that such a compensating chart be used only as a last resort after serious efforts have been made to minimize inspection error. Areas where inspection improvement efforts are likely to pay off include inspection station design, improved communications including feedback, tool and technique improvement, and inspector selection. Even more than these, inspector training or retraining will almost always be worthwhile--especially when judgment is an integral part of the inspection task. A superior treatment of causes and cures for inspection error is presented in [16]. Also, an excellent treatment of human inspection performance is available in [5].



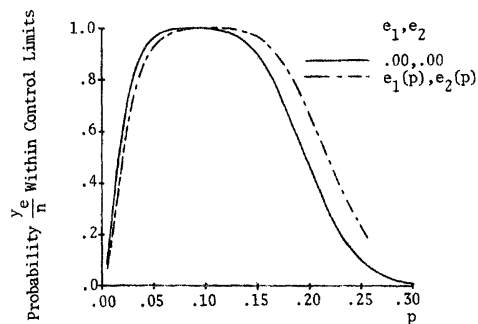


Figure 5: Example 5 OC Curve (Using Biegel [2] Variable Error Rates)

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1. INTRODUCTION

Roberts (5) introduced some control charts based on geometric moving averages (GMA) to add sensitivity in detecting small shifts in a process average. Here we discuss an interesting connection between the GMA and time series forecasting. We also introduce some modified charts based on weighted averages and discuss their use in checking forecast stability.

In Section 2 we describe the GMA briefly as given in Roberts (5) and Bather (3). Section 3 shows (i) GMA as a one step ahead forecast and (ii) a Control Chart for checking forecast stability. Some generalisations of the results in Section 3 are given in Section 4.

2. THE GEOMETRIC MOVING AVERAGE CHARTS

We suppose that a process is on target μ_0 ($=0$, for convenience) initially and successive measurements Z_t ($t = 1, 2, \dots$) are taken (it could even be average of several measurements taken at time t) to check whether there is a shift from the target. Then, following a suggestion from J.W. Tukey, Roberts (5) proposes to use a control chart based on the statistic

$$g_t = r[Z_t + (1-r)Z_{t-1} + \dots + (1-r)^{t-1}Z_1], \quad t \geq 0 \quad (2.1)$$

which is a geometric mean of all the observations Z_t, Z_{t-1}, \dots, Z_1 with Z_t the most recent observation getting the greatest weight ($=r$)^t and all previous observations weights decreasing in geometric progression. Assuming that Z_t is drawn independently from a normal distribution with variance σ_z^2 and that t is sufficiently large so that $\sigma_g^2 \approx [r/(2-r)]\sigma_z^2$, one could form a control chart quite similar to the ordinary Shewart⁶ chart. One of the disturbing things here is that r is quite arbitrary and Roberts (5) takes $r = 2/5$ because "it may have wide appeal in practice" (note when $r = 2/5$, $\sigma_g^2 = \sigma_z^2/2$).

Bather (3) arrives at the statistic given in (2.1) through a Bayesian argument. We outline his procedure below. Suppose that a machine whose performance can be effectively represented by a single unknown quantity μ_t , is inspected regularly to see whether the quality of performance is deteriorated. The successive performance levels $\mu_1, \mu_2, \dots, \mu_t$ are tracked by the observations Z_1, Z_2, \dots, Z_t . The machine is assumed to start from a repaired state, i.e. μ_0 has a desired (target) value ($=0$, for convenience). The operation continues until a decision is made to overhaul it in which case the level is set to zero instantaneously and the whole sequence begins again. This resetting after overhaul may be subject to error and so it is assumed that μ_0 is $N(0, v_0)$ (normally distributed with mean zero and variance v_0) and each subsequent state of repair is drawn independently from this distribution. Now assuming that $\mu_t - \mu_{t-1}$ are drawn independently from $N(0, \sigma^2)$ and that Z_t is $N(\mu_t, \sigma^2)$ Bather (3) shows that the posterior distribution of μ_t given Z_t, Z_{t-1}, \dots, Z_1 is $N(u_t, v_t)$ where the posterior mean $u_t = E(\mu_t | Z_t, Z_{t-1}, \dots, Z_1)$ is sufficient for Z_t, \dots, Z_1 . He also shows that

$$u_t = (1-q)[Z_t + qZ_{t-1} + \dots + q^{t-1}Z_1] \quad (2.2)$$

where q is a function of σ^2 and $\sigma\mu^2$. The statistic g_t and u_t are the same when $r = 1-q$. Now successive decisions can be made by means of a control chart on which the values u_1, u_2, \dots, u_t are plotted until a point falls inside a stopping region indicating that an overhaul is needed.

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3. GMA AND FORECAST STABILITY

As before we suppose that observations $Z_1, Z_2, \dots, Z_t, \dots$ are made at regular intervals and the underlying structure can be represented by a time series model

$$Z_t - Z_{t-1} = a_t - \theta a_{t-1}, \quad |\theta| < 1, \quad t = \dots, -1, 0, 1, \dots \quad (3.1)$$

where $\{a_t\}$ is a sequence of independent identically distributed random variables with $N(0, \sigma_a^2)$. When $\theta = 0$ this is the so called random walk model. We consider (3.1) here because it has been used to represent a wide variety of economic and industrial time series.

The model (3.1) can be re-written as (see for example Abraham and Box (1))

$$Z_{t+1} = f_t + a_{t+1} \quad (3.2)$$

where

$$f_t = (1 - \theta)[Z_t + \theta Z_{t-1} + \dots + \theta^{t-1} Z_1 + \dots] \quad (3.3)$$

and when t is sufficiently large f_t is the same as u_t with $q = \theta$. Now the minimum mean square error (mmse) forecast of Z_{t+1} from t is the conditional expectation of Z_{t+1} given Z_t, Z_{t-1}, \dots (see Box and Jenkins (4)). This is given by

$$E(Z_{t+1} | Z_t, Z_{t-1}, \dots) = f_t \quad (3.4)$$

which is an exponentially weighted average (EWA) or GMA of Z_t, Z_{t-1}, \dots . For computational purposes f_t can also be written as

$$f_t = \theta f_{t-1} + (1 - \theta) Z_t \quad (3.5)$$

implying that the computation can be done recursively as a new observation becomes available. Here one can obtain estimates $(\hat{\theta}, \hat{\sigma}_a^2)$ of (θ, σ_a^2) using time series estimation techniques (see Box and Jenkins (4)) and this eliminates the arbitrariness of $r = (1 - \theta)$ which Roberts (5) had to cope with.

Since f_t also represents the level of the series at time t one could plot it successively on a control chart to see whether there is a drift in the level. Here, however, we will consider another important problem namely the checking of forecast stability. One may be using f_t as the one step ahead forecast when in fact the parameter θ in the model (3.1) has changed or the model (3.1) itself may have changed at some point in time. This could lead to (i) forecasts which don't have minimum mean square error and (ii) forecast errors which are autocorrelated. We refer to them as forecast instability.

Suppose that the model remains the same. Then $a_{t+1} = Z_{t+1} - f_t$, the one step ahead forecast errors are drawn independently from $N(0, \sigma_a^2)$. Hence one could monitor these a_t 's to see whether or not the model is changing.

If there is a parameter change at $(t+1)$ the model may be written as

$$Z_{t+1} - Z_t = a_{t+1} - (\theta + K)a_t \quad (3.6)$$

where K is the amount by which θ is changing. Now (3.6) can be re-written as

$$Z_{t+1} = f_t + A_t \quad (3.7)$$

where $A_t = d_t + a_{t+1}$ and d_t depends on $\theta, K, Z_t, Z_{t-1}, \dots$. In this case $E(A_t) \neq 0$ and A_t 's are autocorrelated. Hence we propose to use the following simple Shewart Chart to detect forecast stability.

- Step 1. Obtain $(\hat{\theta}, \hat{\sigma}_a^2)$ and some action limits based on $\hat{\sigma}_a$ (probably $2\hat{\sigma}_a$ units away on either side of 0).
- Step 2. Plot $Z_{t+1} - f_t$ successively until a point falls outside the action limits or some autocorrelation among the a_t 's is noticeable.
- Step 3. Modify the model to get the minimum mean square error forecast.

Construction of a Shewart Chart is proposed here because of its simplicity. However when more sensitivity is required (which is often the case in forecasting) one should probably use a cusum chart (see Barnard (2)) based on the forecast errors a_t .

4. A MORE GENERAL MODEL, WA AND r_1 CHARTS

Now we generalise the structure given in (3.1) and consider the observations to be generated from an Autoregressive Integrated Moving average model of order (p,d,q) defined as

$$\phi(B)\nabla^d Z_t = \theta(B)a_t, \quad t = \dots -1, 0, 1, \dots \quad (4.1)$$

where $\phi(B) = 1 - \phi_1 B - \dots - \phi_p B^p$, $\theta(B) = 1 - \theta_1 B - \dots - \theta_q B^q$, $\nabla = 1 - B$, B is a backward shift operator defined as $BZ_t = Z_{t-1}$ and a_t is as defined in Section 3. It is also assumed that the roots of $\phi(B)\theta(B) = 0$ lie outside the unit circle. The model (4.1) can be re-written as

$$Z_{t+1} = a_{t+1} + \sum_{i=1}^{\infty} w_i Z_{t+1-i} \quad (4.2)$$

where the weights w_i satisfy the relation

$$\theta^{-1}(B)\phi(B)(1-B)^d = w(B) = 1 - w_1 B - w_2 B^2 - \dots \quad (4.3)$$

As before the mmse forecast of Z_{t+1} from t is

$$f_t = E(Z_{t+1} | Z_t, Z_{t-1}, \dots) = \sum_{i=1}^{\infty} w_i Z_{t+1-i} \quad (4.4)$$

Also one can show that $\sum_{i=1}^{\infty} w_i = 1$ implying that f_t is a weighted average. In any real situation one has only Z_t, Z_{t-1}, \dots, Z_1 and hence one could take f_t as $\sum_{i=1}^t w_i Z_{t+1-i}$. This approximation is not unreasonable because we expect the weights w_i to die out fast (the roots of $\phi(B)\theta(B) = 0$ lie outside the unit circle).

The procedure outlined in Section 3 can now be adopted to check forecast stability.

- Step 1. Estimate $(\phi, \theta, \sigma_a^2) = (\phi_1, \dots, \phi_p, \theta_1, \dots, \theta_q, \sigma_a^2)$ using Time Series estimation techniques (see Box and Jenkins (4)) and obtain action limits based on $\hat{\sigma}_a$.
- Step 2. Calculate the one step ahead forecast f_t of Z_{t+1} using one of the techniques (difference equation approach) given in (4). The formulae (4.4) or its approximation is not best suited for successive computation.
- Step 3. Plot the points $Z_{t+1} - f_t$ successively.
- Step 4. When a point falls outside the action limits or when some autocorrelation among the a_t 's is noticeable, the underlying model needs modification.

The chart described here will be referred to as a Weighted Average (WA) Chart. The forecasting system can be designed, without much difficulty, such that the WA Chart is constructed and the points $Z_{t+1} - f_t$ is plotted automatically by a computer, after the estimation stage in Step 1.

Now we indicate the possible use of another chart which we refer to as the First Lag Autocorrelation (r_1) Chart, to monitor whether or not there is autocorrelation among the one step ahead forecast errors (see Step 4). Here we propose to plot

$$r_1 = \sum_{i=2}^t a_i a_{i-1} / \sum_{i=1}^t a_i^2 \quad \text{successively on a control chart to see whether the first lag}$$

autocorrelation is significantly different from zero. Action limits may be placed on either side of zero at a distance of $2.S.E(r_1)$ where $S.E(r_1) \approx 1/\sqrt{t}$. Ideally one should check the first few autocorrelations. However, to keep the complexities to a minimum, it would probably be enough for our purposes to monitor r_1 alone.

It should be noted that the r_1 chart itself may not be enough in a given situation because, in general, there will be some lag between the times at which the change actually happened and at which the change is noticed in the r_1 chart. Hence we favour the use of the WA and r_1 charts simultaneously.

*when d is equal to or less than one

5. CONCLUDING REMARKS

The charts based on GMA as described in Roberts (5) is more complex than the Standard Control Charts and this complexity may not, in many cases, be compensated by the added sensitivity. However, if the observations have a structure as in (3.1) the mmse one step ahead forecast is a GMA and the new chart based on this to check forecast stability is relatively simple and very interesting. The more general structure in Section 4 leads us to WA and r_1 charts which seem to be very promising.

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VARIABLES ESTIMATES OF PERCENT DEFECTIVE

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ONE-SIDED SPECIFICATION LIMITS

We start by considering example D-2, p.90 of MIL-STD 414. "The specified minimum yield point for certain steel castings is $L = 58,000$ psi. The variability σ is known to be 3,000 psi. The yield points of a sample of size $n = 10$ are 62,500; 60,500; 68,000; 59,000; 65,500; 62,000; 61,000; 69,000; 58,000; 64,500." On the basis of this sample, we wish to estimate the fraction defective in the lot from which the sample was drawn.

The recommended procedure is to compute the quality index

$$Q_L = \frac{(\bar{x} - L)}{\sigma} \sqrt{\frac{n}{n-1}},$$

where \bar{x} is the sample mean, and estimate the fraction defective P_L as the probability corresponding to the normal deviate $z = -Q_L$, i.e.,

$$\hat{P}_L = F(-Q_L) = F(z) = \int_{-\infty}^z \exp(-t^2/2) dt / \sqrt{2\pi}$$

For the example above

$$Q_L = \frac{(63,000 - 58,000)}{3,000} \sqrt{\frac{10}{9}} = 1.76,$$

$$P_L = .0392 = F(-1.76)$$

A more natural, but naive, approach to the estimation of P_L is to note that if μ is the lot mean then,

$$P_L = F\left(\frac{\mu - L}{\sigma}\right)$$

Thus, since \bar{x} is an estimate of μ

$$\bar{P}_L = F\left(\frac{\bar{x} - L}{\sigma}\right)$$

would be a intuitive estimate of P_L . For the example, this gives the estimate

$$\bar{P}_L = F\left(\frac{58,000 - 63,000}{3,000}\right) = F(-1.6667) = .0482.$$

This differs from the recommended estimate

$$\bar{P}_L = .0392$$

by almost 1% defective.

The estimate \hat{P}_L , as derived in reference (1), is a minimum variance unbiased estimator, and thus has many good "large sample" qualities. On the other hand, an examination of the distribution of \hat{P}_L indicates that other estimators have properties which are better in certain circumstances.

THE DISTRIBUTION OF \hat{P}_L

Let X_1, X_2, \dots, X_n be an independent random sample from a lot which is normally distribution with mean μ and standard deviation σ . Let Z be a $N(0,1)$ variable with density function

$$f(z) = \exp(-z^2/2) / \sqrt{2\pi}$$

and distribution function

$$F(z) = \int_{-\infty}^z f(z) dt \quad .$$

The fractile points $z(t)$ are defined as $t = F(z(t))$.
Let L be the lower specification limit for the lot, then

$$P_L = F(z(P_L))$$

where

$$Z(P_L) = Z(L) = \frac{L-\mu}{\sigma}$$

The estimator \hat{P}_L is defined as

$$P_L = F\left(\frac{-\bar{x}+L}{\sigma} \sqrt{\frac{M}{n-1}}\right)$$

which is distributed as

$$\hat{P}_L = F\left(\frac{uz(L) - Z}{\sqrt{n-1}}\right)$$

where Z is $N(0,1)$.

The distribution function of \hat{P}_L is then

$$\begin{aligned} G(t) &= \text{Prob}(P_L < t) \\ &= \text{Prob}\left(F\left(\frac{\sqrt{n}z(L) - Z}{\sqrt{n-1}}\right) < t\right) \\ &= \text{Prob}\left(\frac{\sqrt{n}z(L) - Z}{\sqrt{n-1}} < z(t)\right) \\ &= F(\sqrt{n-1} z(t) - \sqrt{n} z(L)), \end{aligned}$$

and the density function is

$$\begin{aligned} f(t) &= dG(t)/dt \\ &= \sqrt{n-1} f(\sqrt{n-1} z(t) - \sqrt{n} z(L)) dz(t)/dt \\ &= \sqrt{n-1} \exp(-((n-2)z(t)^2 - 2\sqrt{n}\sqrt{n-1} z(t)z(L) + nz(L)^2)/2) \end{aligned}$$

where, as before, $t = F(z(t))$.

From the distribution function we note that $F(t) = .5$ implies that

$$\begin{aligned} \sqrt{n-1} z(t) - \sqrt{n} z(L) &= 0 \\ z(t) &= \sqrt{\frac{n}{n-1}} z(L) \\ t &= F\left(\sqrt{\frac{n}{n-1}} z(L)\right) \end{aligned}$$

that is,

$$\text{median } \hat{P}_L = F\left(\sqrt{\frac{n}{n-1}} z(L)\right) \neq P_L$$

The estimator whose median is P_L

$$P_L = F\left(\frac{L-\bar{x}}{\sigma}\right),$$

The density function may be represented as

$$g(t) = \sqrt{n-1} \exp\left(-\left(\frac{n-2}{2}\right)(z(t) - \frac{\sqrt{n}\sqrt{n-1}}{n-2} z(L))^2 + \frac{n}{n-2} \frac{z(L)^2}{2}\right)$$

from which it is obvious that the mode occurs when

$$z(t) = \frac{\sqrt{n(n-1)}}{n-2} z(L)$$

$$t = F\left(\frac{\sqrt{n(n-1)}}{n-2} z(L)\right) .$$

Hence an estimator whose mode is P_L is

$$\hat{P}_L = F\left(\frac{n-2}{n-1} \frac{L-\bar{x}}{\sigma}\right).$$

For the example data the three estimators are

$$\hat{P}_L = F\left(\sqrt{\frac{n}{n-1}} \frac{L-\bar{x}}{\sigma}\right) = F(-1.76) = .0392$$

$$\bar{P}_L = F\left(\frac{L-\bar{x}}{\sigma}\right) = F(-1.67) = .0475$$

$$P_L = F\left(\frac{n-2}{n-1} \frac{L-\bar{x}}{\sigma}\right) = F(-1.48) = .0694$$

Figure 1 shows the density function of \hat{P}_L for samples of size $n = 10, 20, 50$ from a 10% defective lot ($P_L = .10$). The mean, median and mode for these densities are

	n=10	n=20	n=50
mean	.10	.10	.10
median	.088	.094	.10
mode	.064	.083	.093

TWO-SIDED SPECIFICATION LIMITS

When both upper and lower specification limits (U and L) are given the unbiased, minimum variance estimator for P , the lot fraction defective is

$$\hat{P} = \hat{P}_L + \hat{P}_U = F\left(\frac{L-\bar{x}}{\sigma} \sqrt{\frac{n}{n-1}}\right) + F\left(\frac{\bar{x}-U}{\sigma} \sqrt{\frac{n}{n-1}}\right)$$

This is merely the sum of the estimates of the fraction outside the individual limits.

For the example data, with upper specification limit $U = 67,000$ psi (this is example D-3, p.97, MIL-STD 414). The estimates are

$$\hat{P}_L = F\left(\frac{63,000-58,000}{3,000} \sqrt{\frac{10}{9}}\right) = F(-1.76) = .0392$$

$$\hat{P}_U = F\left(\frac{67,000-63,000}{3,000} \sqrt{\frac{10}{9}}\right) = F(-1.41) = .0793$$

$$\hat{P} = \hat{P}_L + \hat{P}_U = .0392 + .0793 = .1185$$

It may be noted that since $U - L = 3\sigma$, the minimum lot fraction defective occurs at $\mu = (U+L)/\sigma$ and equals

$$P_L + P_U = F(-1.5) + F(-1.5) = .1336 .$$

The minimum estimate occurs when $\bar{x} = 63,000$ and is

$$P = 2F\left(-1.5\sqrt{\frac{10}{9}}\right) = .1164 ,$$

a seeming contradiction.

The distribution function of \hat{P} is given by

$$\begin{aligned} G(t) &= \text{Prob}(\hat{P} < t) = \text{Prob}(\hat{P}_L + \hat{P}_U < t) \\ &= \text{Prob}(F((L-\bar{x})V/\sigma) + F((\bar{x}-U)V/\sigma) < t) \\ &= \text{Prob}\left(F\left(\frac{\sqrt{n}z(L)-Z}{\sqrt{n-1}}\right) + F\left(\frac{\sqrt{n}z(U)+Z}{\sqrt{n-1}}\right) < t\right) \end{aligned}$$

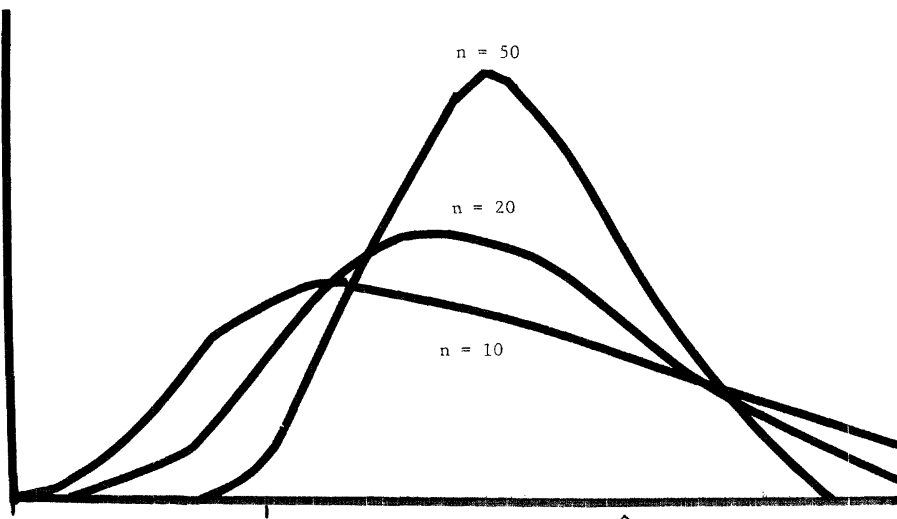


Figure 1. Density functions for \hat{P}_L
 $(P_L = .10, n = 10, 20, 50)$

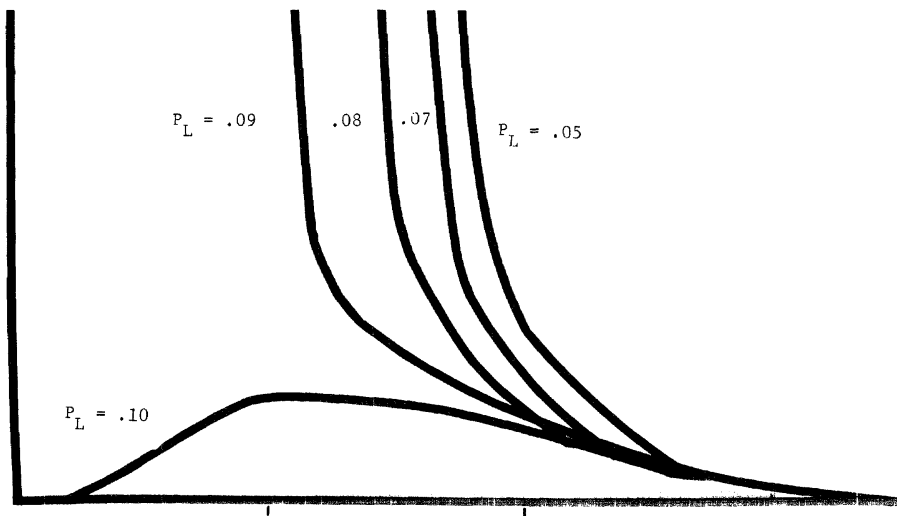


Figure 2. Density functions for \hat{P} .
 $(P = P_L + P_U = .10, n = 10)$

where, as before

$$F(z(L)) = P_L, F(z(U)) = P_U, P = P_L + P_U$$

$$Z \text{ is } N(0,1)$$

$$V = \sqrt{n/(n-1)}.$$

Since \hat{P}_L and \hat{P}_U are both unbiased, it automatically follows that

$$E(\hat{P}) = E(\hat{P}_L) + E(\hat{P}_U) = P_L + P_U = P$$

and hence \hat{P} is unbiased.

The minimum value of \hat{P} occurs when $Z = \sqrt{n}(z(L) - z(U))/2$, hence,

$$\hat{P}_{\min} = 2F(V(z(L) + z(U))/2)$$

TABLE I

Characteristics of some 10% defective lots
($P=.10$, $n=10$)

P_L	P_U	$z(L)$	$z(U)$	\hat{P}_{\min}
.10	.00	-1.281	$-\infty$	0.000
.09	.01	-1.341	-2.326	.053
.08	.02	-1.405	-2.054	.068
.07	.03	-1.476	-1.881	.077
.06	.04	-1.555	-1.751	.081
.05	.05	-1.645	-1.645	.083

From the form of $G(t)$, it is obvious that if $Z = z(t)$ is a solution of

$$F\left(\frac{\sqrt{n} z(L) - Z}{\sqrt{n-1}}\right) + F\left(\frac{\sqrt{n} z(U) + Z}{\sqrt{n-1}}\right) = t$$

then $z^*(t) = -z(t) + \sqrt{n}(z(L) - z(U))$ is also a solution.

The density function of \hat{P} is

$$g(t) = dG(t)/dt$$

$$= \sqrt{n-1} \frac{f(z(t)) + f(z^*(t))}{\left| f\left(\frac{z(t) - \sqrt{n}z(L)}{\sqrt{n-1}}\right) - f\left(\frac{z(t) + \sqrt{n}z(U)}{\sqrt{n-1}}\right) \right|},$$

for t between $t = \hat{P}_{\min}$ and $t = 1$.

Figure 2 shows the density functions of the lots listed in TABLE I. In each case the density function is infinite at $P = \hat{P}_{\min}$.

VARIABILITY UNKNOWN

Where the lot standard deviation σ is unknown, the sample standard deviation

$$s = \sqrt{\frac{\sum (x - \bar{x})^2}{n-1}}$$

must be used. The statistics

$$Q_L = \frac{\bar{x} - L}{s}, Q_U = \frac{U - \bar{x}}{s}$$

are used in place of

$$\frac{\bar{x}-L}{\sigma} \sqrt{\frac{n}{n-1}}, \frac{U-\bar{x}}{\sigma} \sqrt{\frac{n}{n-1}}$$

the factor $\sqrt{n/(n-1)}$ is included in table B-5, which gives the unbiased estimates of the fraction defective.

The estimators \hat{P}_U and \hat{P}_L are functions of the non-central t-distribution and a discussion of their properties will be published elsewhere. One peculiarity which might be noted is that if

$$Q_L = \frac{\bar{x}-L}{\sigma} < -\frac{(n-1)}{\sqrt{n}}$$

then $\hat{P}_L = 1$ and conversely if

$$Q_L = \frac{\bar{x}-L}{\sigma} > \frac{n-1}{\sqrt{n}}$$

then $\hat{P}_L = 0$.

MATHEMATICAL NOTES

The standard attributes estimator for the fraction defective is

$$P_L^* = d/n$$

where d is the number of defectives (values of $x < L$) in a random sample of size n. The corresponding unbiased minimum variance attributes estimator as given by Blackwell (ref. 1) is

$$\hat{P}_L = E(P_L^* | T)$$

Where T is sufficient for P_L , i.e. $T = \bar{x}$ if σ is known and $T = (\bar{x}, s)$ if σ is unknown. Derivation of the properties of \hat{P}_L , as used in MIL-STD 414, are given in references (2) and (6). The variance of \hat{P}_L is given by Owen (3) in the case σ is known and by Wheeler (4) when σ is unknown. The density functions given here appear to be new.

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STATISTICS APPLIED TO AND BY QC CIRCLES

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INTRODUCTION

Statistical methodology and the QC Circle are inseparable. The QC Circle was founded upon the principles of problem solving. Consequently, statistical tools form an integral part of Circle activity. The authors first review these various tools and then discuss the need for statistical theory in the development of new tools for application by Circles. Finally, a call is made for research into the QC Circle phenomenon itself.

THE QC CIRCLE

The QC (Quality Control) Circle is a group of individuals whose function is the furtherance of quality control. It is a small group of about five to ten members. Usually the membership is comprised of people who work together as in one section of an assembly line, a machine shop, or department. Most QC Circles operate at the level of foreman together with hourly paid personnel; however, some Circles are formed at higher levels such as a Circle of engineers in Lockheed Missiles and Space Company⁽¹⁾. Generally the leader of a Circle is the foreman or assistant foreman although, as at Honda Motor Company⁽²⁾, there may be a deliberate attempt to encourage operating personnel as leaders. The Circles meet on a regular formal basis from one hour per month to as frequently as one hour per week. An essential ingredient of the QC Circle is the voluntary aspect of membership; no one is forced to join, although the Circles and management may encourage participation. (Even in Japan where one might think that 100% participation occurs, this simply is not true. The author and his wife were given the opportunity at Honda Motor Company to sit in on a meeting of foremen who were addressing the question--How may Honda encourage non-participating employees to join QC Circles?)⁽³⁾

The QC Circle's sole objective is to solve work-related problems. The term "QC" is technically a misnomer because the Circles will address a variety of problems other than those which are commonly considered to be under the domain of quality control. The QC Circles in Japan were estimated to spend about 50% of their effort on quality control.⁽⁴⁾ Reduction in costs and productivity increases together accounted for 40% of the effort and there were a variety of other areas of endeavor. It is important to see that the Circles concentrate on the solution of technical problems; they never address salary or other issues which lie in the bailiwick of management and organized labor.

It is well worth noting that QC Circles themselves carry through the complete problem solving process of:

- a. identifying problems,
- b. deciding what problems to address,
- c. solving that problem,
- d. implementing their solution, and
- e. maintaining the solution.

It is essential to recognize this problem solving feature in QC Circles in order to differentiate this activity from other concepts such as the Product Teams in Sweden or the suggestion system.

HISTORY OF QC CIRCLES

The QC Circle originated in Japan in 1961.⁽⁵⁾ The entire scope of events which led to its beginning is much too broad to fully describe in this paper, yet, a brief review may overemphasize some aspects and neglect other essentials. Dr. Ishikawa remarks that the QC Circle is a "logical development of our endeavor of breaking through the above stated barriers which have confronted Japanese industry at large."⁽⁶⁾ (See reference for the list of seven barriers.) In addition, several salient points may be made. First, the Circle is seen as a way to enhance the development of the foreman as well as the operators (hourly paid employees). Secondly, the Circle provides an opportunity for the foreman together with operators to actively improve their own job by means of solving work-related problems. Thirdly, the problem solving nature of Circle activity serves as an outlet for a basic human need: creativity. An off-shoot or fall-out of this creativity outlet is that the Circle activity gets to the heart of motivation. Fourth, the problem solving activity of the Circle increases the profitability and productivity of the firm.

Contrary to some opinions, the United States has supplied many of the "building blocks" out of which the QC Circle was constructed. Dr. Joseph Juran and Dr. W. Edwards Deming were invited to give a series of lectures and seminars on the management of quality control and statistical methodology, respectively. It is from these inputs, Japan's commitment to quality, and the threefold objective of the QC Circle to

1. contribute to the improvement and development of the enterprise,
2. respect humanity and build a worthwhile to live and happy bright workshop,
3. display human capabilities fully and eventually draw out infinite possibilities "⁽⁷⁾

that the QC Circle emerged in 1961. A phenomenal training effort took place in Japan: radio and TV courses; seminars both within and outside companies; and magazines and journals. Tremendous growth in numbers of QC Circles has taken place, until, the number of Japanese QC Circles registered at the JUSE (Union of Japanese Scientists & Engineers) was approximately 70,000 in 1975. With about ten members per Circle, this means that about 700,000 operators and foremen are actively engaged in solving work-related problems. Moreover, estimates have been made that ten times this number are really involved, since possibly only 10% of the Circles are registered.

From the inception of QC Circles in 1961, the concept has jumped national and cultural boundaries. Today Circles are active in South Korea, Taiwan, Singapore, Brazil⁽⁸⁾, Mexico⁽⁹⁾, the United States⁽¹⁰⁾, and in Holland⁽¹¹⁾.

STATISTICS USED BY QC CIRCLES

The immediate objective of a QC Circle is the solving of work-related problems. The framework of a sequence of steps in this problem solving process is shown in Figure 1.

Identify Goals

The first step is the identification of goals. This thrust may come from management or may arise from within the Circle. When the goal is broadly defined, such as the reduction of defects in a particular department, then the need arises to identify the component problems. Next, choices must be made as to which components are to be tackled first. At this stage data collection becomes essential.

Data Collection

The Circle must understand several aspects of data collection: the purposes of collecting data; is it correct data such that the structure will be revealed; the kinds of data; organization of data; and how to prepare before collecting data.⁽¹²⁾

The Japanese, in their insistence that the QC Circle carefully and purposefully collect data, seem to have grasped a basic principle put forth by the late eminent statistician, Sir Ronald A. Fisher. Professor Fisher in his book Design of Experiments states: "Statistical procedure and experimental design are only two different

aspects of the same whole ..."(13) When the QC Circle collects data, it does so by design - by predetermined plan - and the data is collected so that a proper interpretation of the facts can be achieved through analysis of the data: this is statistical procedure in the fullest sense.

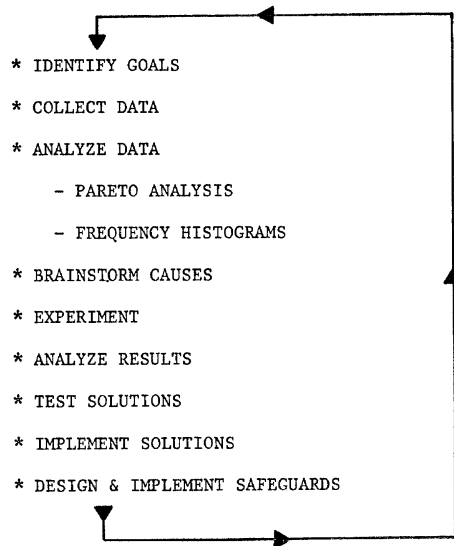


FIGURE 1. Problem Solving Sequence

Pareto Analysis

Pareto analysis is one of the most important techniques used by QC Circles since it serves to keep the attention on the most serious, and potentially most rewarding problems.⁽¹⁴⁾ The four major ingredients of this technique are:

- a desire to effect improvement
- data collection
- summarization of the data in a Pareto Chart (see Figure 2)
- follow through on the biggest problem as identified on the Pareto Chart.

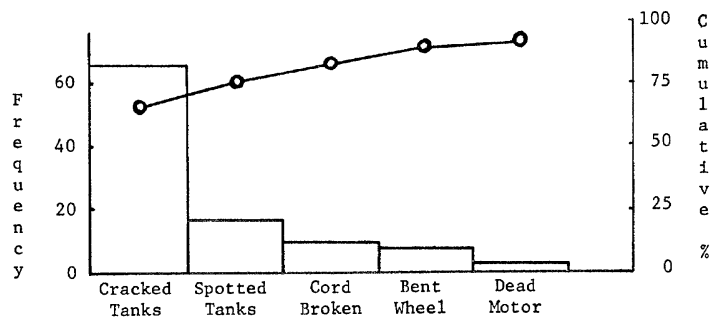


FIGURE 2. Pareto Diagram

Commonly only items (b) and (c) would be considered the technical aspects of Pareto analysis; however, the analysis will be viewed as a sterile exercise unless ingredients (a) and (d) are included.

Frequency Histogram

Frequency histograms are a second analytical tool used by the QC Circle on data. The histograms will show distribution type, centering, variation and any abnormalities. When the specifications are drawn on the histogram, the Circle will be able to see not only the process capability but also the ability of the process to meet the specifications. (See Figure 3)

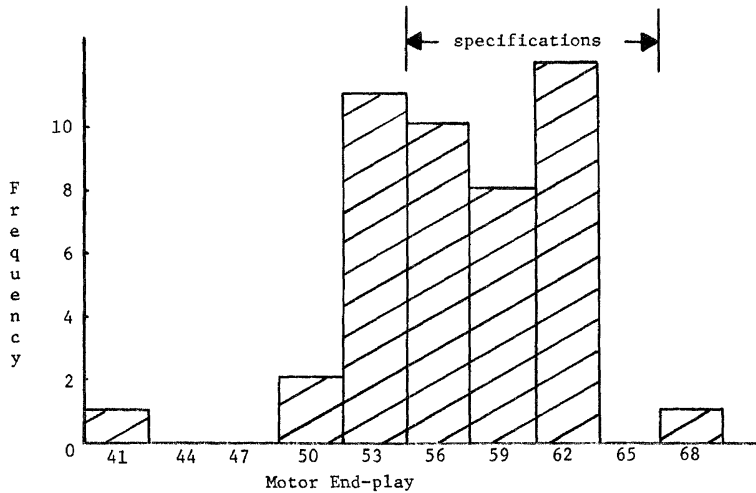


FIGURE 3. Frequency Histogram

The usefulness to the Circle of the frequency histogram is due to several factors: simplicity of the histogram; ease of construction; effortless interpretations; and power of the tool to show process capability with respect to specifications.

Check Sheets

The check sheet is a form for the collection of data. It is designed so that it may be easily used and the data "organized automatically." As illustrated in Figure 4, the Circle may use the check sheet to assure that the data are collected in such a way that the check sheet will reveal several features: machine, shift, and day. Then it is an easy matter to sum up the data within each of the categories and then examine it for major differences.

	Shift	Mon	Tue	Wed	Thur	Fri	Totals
Machine A	1	x	xx		x		4
	2		x				1
Machine B	1	xx	xxxx	xxx	x	xxx	13
	2		x		x		2
Totals		3	8	3	3	3	20

FIGURE 4. Check Sheets

Cause and Effect Diagram

The C&E (Cause and Effect) Diagram is the product of brainstorming. As shown in Figure 5, the problem is identified at the right end of the main spine. The QC Circle through brainstorming identifies possible causes of the problem.⁽¹⁵⁾ Generally, these causes can be classed under subbones of method, men, machine, and material. Although not commonly considered to be a statistical technique, the C&E Diagram is an essential component of the problem solving process used by the QC Circle, because it is a method by which brainstorm data can be recorded and organized.

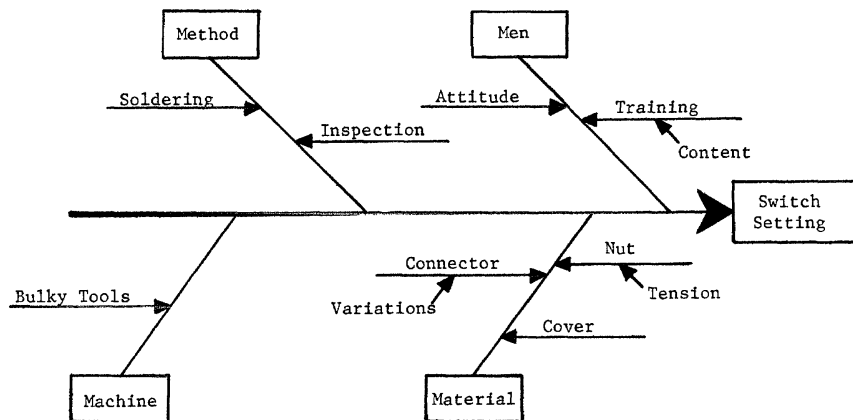


FIGURE 5. Cause and Effect Diagram

Graphs

The Circle needs to be familiar with the purposes of several kinds of graphs and capable of preparing these graphs. These include: time series graphs of productivity, costs, percent defects; histograms; Pareto charts; pie charts; and bar graphs. Basically there are two purposes served by graphs. First, the Circle uses the graph for analysis, to see what has happened. Secondly, the graph is one of the most effective devices for communicating information. Reporting writing by QC Circles is a very real and necessary activity, especially to keep management apprised of its accomplishment. (At one of the plants of Honda Motor Company the author was shown a section of notebooks filled with QC Circle reports. The notebooks, side by side, filled about two feet of bookshelf and represented only a six month time period at that one plant!)

Other Statistical Tools

The QC Circle will employ various other statistical concepts such as statistical control charts, scatter diagrams, binomial probability paper, random sampling, and acceptance sampling.⁽¹⁶⁾ Dr. Ishikawa states that these techniques, as well as the previously mentioned ones, are to be used by QC Circles, "The techniques in this book are those which we feel should be known by all QC Circle leaders and, if possible, all Circle members as well."⁽¹⁷⁾ A variety of other, more advanced statistical techniques are employed by some Circles, such as experimental design. However, these tools are less known and infrequently used by Circles.

Degree of Training

In Japan there is a massive educational effort to teach the methods and concepts of quality control and QC Circles. A brief description of some of the courses offered by the JUSE will summarize this.⁽¹⁸⁾ Two courses are designed for general foremen, foremen, and assistant foremen: a six day, QC Basic Course for Foremen, and an eight day advanced course, QC Application Course for Foremen. Both courses emphasize quality control methodology including the solving of problems using the statistical tools we

have already mentioned. Both courses incorporate material on the QC Circle. The QC Basic Course for Group Leaders is a three-day course for assistant foremen, QC Circle leaders, and other leaders; it covers basic group problem solving. A variety of other courses are also available: a correspondence course; industrial engineering course; within-company courses; etc.

In the United States a variety of courses have been available which teach many of the basic problem solving concepts. However, the clearly defined and complete problem solving methodology, which we described earlier, has generally not been available. The exceptions are noteworthy. First, Dr. Joseph Juran has covered the basic problem solving sequence.⁽¹⁹⁾ Secondly, the QC Circle training done at Lockheed Missiles and Space Company and that done by Wayne Rieker⁽²⁰⁾ as well as Jeff Beardsley⁽²¹⁾ includes a one- to two-week training period for the QC Circle facilitator. The facilitator in turn trains the foremen or Circle leaders through a similar course. Finally, the Circle members, who are hourly paid employees, are instructed in a basic teaching/application course which may be given in one-hour sessions over a several month period.

DEVELOPMENT OF NEW STATISTICAL METHODS FOR USE BY QC CIRCLES

The development of new statistical methods for use by QC Circles has to meet several stringent conditions. First, the concept must be easily teachable to the Circle leaders and members, hence it cannot be a concept which presupposes either a strong statistics or mathematics background. Secondly, it must be relevant to the kinds of tasks which Circles undertake (a non-parametric test for the study of stock market quotations would not be appropriate in a production facility). Thirdly, it must offer sufficient advantage over existing tools to warrant bringing it into training courses, journals, and other means of transmitting the concept to the Circles. Finally, the tool must be robust so that it will apply as a good approximation to situations where not all the conditions are completely satisfied.

One example will be given of the kind of technique which may meet the above criteria. This involves a significance test on the Pareto analysis. The essential problem is for a Circle to determine if there are sufficient differences between categories of the Pareto chart to justify the decision to choose the most frequently occurring item as the most important one. From a statistical viewpoint the concern is that the differences in frequencies be more than just random sampling variation. The problem is complicated statistically in that ordinarily the Pareto chart is based upon nominal data. Therefore many of the non-parametric tests based upon interval and ordinal data will not apply. A further complication is that the number of classes is indeterminate. Also, some Pareto charts are based on criteria other than frequency, such as dollars; this may prove to be a very knotty complication.

Other potential examples of new theory and/or new applications of statistics by QC Circles include the following: simplified methods for analyzing designed experiments since the analysis of variance is too sophisticated for use by Circles; and the corner test for association which provides a simple significance test for correlation.

APPLICATION OF STATISTICS TO QC CIRCLES

In order to provide management with a viable, accurate model of the role which QC Circles play in industries and institutions, it is necessary that methods be developed to answer two questions. First, what are the effects upon QC Circles of various factors: unionization, skill levels, size of firm, type of firm, type of work, culture, management philosophies, etc. Virtually nothing has even been attempted in evaluating how these factors affect QC Circles. To a large extent the problem can be handled only through surveys. Some factors, such as skill levels and type of work, may be amenable to designed experiments.

A second type of factor which is expected to affect QC Circles is that over which management has some control. A good example would be training. At this point in time we do not have even a rough, quantifiable model showing the relationship of amount and type of training to success of the Circles. Because of the heavy cost of training, such a model would be of considerable value. This kind of factor should be relatively easy to evaluate using designed experiments. For example, within one particular industrial plant, new Circles could be randomly selected for differing training programs.

A randomized block design⁽²²⁾ seems appropriate here.

The second major area of applications of statistics to QC Circles is to answer the question: what are the results of QC Circles? QC Circles can be expected to reduce rework, scrap and other costs. However, as with any program through time the effects of the Circles are likely to be confounded, or mixed in, with the effects of other factors such as new cost reduction programs, business cycles, etc. It becomes incumbent upon the statistician to devise experiments and surveys which will effectively separate the two types of factors. This is by no means a trivial matter. There may be a need for factorial and fractional factorial experiments to adequately cover this.

This paper has attempted to convey the extent to which statistics applies to QC Circles. The Circles themselves incorporate basic statistical tools as integral parts of their problem solving process. New theory and applications of existing theory need to be developed and placed into the kitbag of Circle tools. Finally, a great deal of intensive, sophisticated investigation is required, both to evaluate the degree to which various factors impinge upon the Circle and to quantify the effects which Circles have upon motivation, productivity and quality.

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CONFIDENCE INTERVALS FOR POPULATION PERCENTILES

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If one has a large size sample from a population that is normally distributed, the calculation of population percentiles is simple and straightforward. The calculation of the mean and standard deviation and the use of the table of standard normal distribution found in any statistical text will quickly yield the desired table of test scores vs. percentile of the population. This situation is, unfortunately, not the usual case. Data is expensive. Frequently the sample size is relatively small and the population distribution often departs from normality, particularly in the tails. The purpose of this paper is to present an algorithm for estimating population percentiles and confidence intervals for the percentiles that is independent of the population distribution and is suitable for use with relatively small size samples.

COMPUTATION ALGORITHM

The term *test score* is used here in the broadest sense. It might be the score attained by an individual on a written test such as the Scholastic Aptitude Test or it might be a *test* consisting of a tabulation of the number of hours absence from work by industrial employees. Other industrial applications include the distribution of machine parts usage for use in deciding stock inventory levels.

1. Obtain the test scores for a random sample of size n from the population of interest.
2. Rank the test scores from smallest to largest, *i.e.* 1 to n .
3. Calculate the cumulative frequency corresponding to each test score, i .
4. Estimate the population percentile corresponding to any given test score by calculating $100i/(n+1)$.
5. Calculate the confidence interval for the population percentile using the binomial confidence limits for the percentage calculated in Step 4.

The estimates of population percentiles and confidence limits can be conveniently plotted on normal probability paper. The linearity of the plot of test score vs. percentile is a measure of the normality of the population if normal paper is used. A derivation of this algorithm is appended.

DISCUSSION

Our daily lives are greatly influenced by test scores that are reported as population percentiles. Reading comprehension tests and achievement tests mark our children's progress in school. SAT scores played an important part in our own educations and largely determine if our older children will obtain college scholarships. Population percentiles are also used in industry. Some examples are productivity standards for employees paid on piece-rates, and hours of employee absence, a factor often used as a basis for performance ratings. Fluctuating parts inventory levels can also be viewed in this context.

My experience indicates that tests like those named above are frequently published and accepted when they are based on a naive understanding of statistical inference. The Central Limit Theorem allows us to use the normal distribution, with comfortable confidence, as a model

for inferences concerning the mean. This generalization, however, does not extend to the parent distribution. It is prudent for us to exercise care in making inferences which are used by others in making decisions. The algorithm presented is nonparametric and therefore quite general. It is suitable for non-normal distributions as well as any that may be normal. The computation of confidence intervals for the quoted percentiles allows a ready assessment of the precision of inference made and prevents the undue assignment of importance to standards based on relatively small samples. On the other hand, the use of confidence limits also permits the use of small samples for limited inferences without being misleading.

APPENDIX DERIVATION OF COMPUTATION ALGORITHM

The cumulative density function, F , is the probability that some randomly drawn sample value, X , is equal to or smaller than stated value, x .

$$F = \Pr (X \leq x)$$

If we draw a random sample of size n from the population:

$$\Pr (\text{All } X \leq x) = F^n$$

The probability that all X are equal to or less than x is the same as the probability that the largest sample value, X_{max} , is equal to or less than x .

$$\Pr (X_{max} \leq x) = F^n$$

Therefore, the cumulative density function of X_{max} is F^n . We wish to find the mean of this distribution. The probability density function is the derivative of the cumulative function:

$$n F^{n-1}$$

The mean, \bar{F} , is the integral of the product of value and density:

$$\begin{aligned} \bar{F} &= \int_0^1 F n F^{n-1} dF \\ &= n F^{n+1} / (n + 1) \Big|_0^1 \\ &= n / (n + 1) \end{aligned}$$

That is to say that, on the average, the maximum value of a sample of size n is located at the $n/(n+1)$ -th fractile of the distribution. By a similar argument, it can be shown that the i -th member in an ordered sample is, on the average, at the $i/(n+1)$ -th fractile of the distribution.

It should be noted that there was no restriction placed on the form of the distribution, F . Therefore, the rule is completely independent of the shape of the distribution.

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HOW TO SELECT THE BEST CONTENDER

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INTRODUCTION

Managers and others in administrative positions are often faced with the problem of selecting the best contender, from a group of contenders. These contenders are often those remaining after preliminary testing or competition in a larger pool of candidates.

The quality of a contender may be described in a qualitative way, or in a quantitative way. For example, if the contenders are types of lightbulb filaments, the best contender may be the type with the longest life; while if the contenders are regimens for treating a particular disease, the best contender may be the one with the highest response rate. Each of these cases involves contenders which can be characterized by a single quantitative parameter. Such cases have received much attention since the pioneering ranking-and-selection work of Bechhofer⁽¹⁾ and of Gupta⁽⁴⁾ in the early 1950's. (For some references and discussion, see Gibbons, Olkin, and Sobel⁽³⁾, Kleijnen⁽⁶⁾, or Dudewicz⁽²⁾.) Our interest here does not lie in such cases.

The cases which do concern us here are those in which either multiple parameters characterize a contender, or qualitative ratings by "experts" are sought and used as a basis for the decision. For example, oncologists base the assessment of therapeutic effectiveness of a cancer treatment method on such multiple parameters as: the curativeness of the method, the disease-free survival time of patients treated, the overall survival time of patients treated, the quality of life, the affordability of the treatment, and so on. As another example, consider the product selection problem: several versions of a new product have survived the developmental phase, and now one must be selected for marketing. Often a number of specially trained judges will then examine and rank the versions (from poor to excellent on a preference scale) on each of several characteristics (e.g., crispness, sweetness, skin texture, aroma, color appeal, and so on). In either of these cases (and many others) the question of how to combine the multiple parameters or multiple preference scores into a single parameter usually has no satisfactory answer. Our interest lies in such cases. (While the selection problem has an obvious solution in the situation where the same contender rates as best on all measures, that situation is so unusual as not to need further mention here.)

As the above examples show, definition of what it means to be the best contestant is usually not at all straightforward in multiple parameter cases. Below we will give such a definition, and discuss procedures for selecting the best contestant using our definition. In the remainder of this paper we will proceed as follows: first, we will discuss these problems in a practical example with real data; second, we will give our definition and procedure; third, we will give mathematical details of our procedure's characteristics.

EXAMPLE: THE WILCOXON AND YODEN PRIZES

Each year, the Chemical Division of the American Society for Quality Control awards the Frank Wilcoxon Prize and the Jack Youden Prize. These Prizes are awarded for articles in Technometrics, the Wilcoxon being for the best practical application paper and the Youden for the best expository paper. In the 1976 competition (held in 1977) for these prizes, all the articles appearing in the 1976 volume of Technometrics formed a pool of candidates and fifty referees selected, from the pool, six articles for the Wilcoxon award competition and seven articles for the Youden award competition. (Both authors of this paper served the Awards Committee, one (EJD) being the Chairman of the committee.)

Merit of each article depends on such qualities as originality, scientific contribution, readability, etc., and preference scores (e.g. from poor to excellent) on such qualities by referees are measurements to determine relative ranks of articles. The difficulty associated with the preference-score method is how to combine preference scores into an acceptable parameter ranking articles. Thus the Awards Committee instead asked referees to rank the final contenders from best to worst according to their judgement on the overall quality of each contender (referees were not mandated to complete the ranking), and as a result we obtained the incomplete rank score matrices of Tables I and II.

TABLE I

Rank Scores of 7 Contenders for the1976 Youden Prize*

Referee	C ₁	C ₂	C ₃	C ₄	C ₅	C ₆	C ₇
1	4	2	1	5	6	0	3
2	2	0	5	1	4	3	6
3	1	5	2	3	6	0	4
4	2	5	6	0	3	1	4
5	1	2	5	3	4	0	6
6	6	2	3	4	5	0	1
7	5	4	1	3	2	0	6
8	2	1	0	6	5	3	4
9	4	5	2	1	3	6	0
10	6	2	3	1	4	0	5
11	4	5	3	2	6	1	0
12	2	3	4	0	1	5	6
13	2	6	-	-	4	3	5
14	2	-	3	6	4	-	5
15	5	4	-	6	2	-	3
16	4	5	-	-	-	3	6
17	6	4	-	5	3	-	-
18	4	5	3	-	-	-	6
19	4	5	-	-	3	-	6
20	3	6	5	-	4	-	-
21	-	6	5	-	-	4	-
22	5	-	-	-	4	-	6
23	-	5	-	-	6	-	-
24	-	-	-	-	6	-	-

TABLE II

Rank Scores of 6 Finalists for the1976 Wilcoxon Prize*

Referee	C ₁	C ₂	C ₃	C ₄	C ₅	C ₆
1	6	2	3	4	1	5
2	2	4	5	3	1	6
3	5	2	4	3	6	1
4	5	6	2	4	3	1
5	2	3	4	1	6	5
6	3	4	2	5	1	6
7	5	1	4	3	2	6
8	2	6	3	5	4	1
9	5	4	3	2	1	6
10	6	5	1	2	4	3
11	4	6	-	3	5	-
12	6	4	5	-	-	3
13	-	-	4	6	3	5
14	3	5	-	6	4	-
15	3	4	-	6	5	-
16	-	4	3	6	-	5
17	5	-	4	6	-	-
18	-	4	6	5	-	-
19	-	4	-	5	-	6

*The referee numbers are arranged for convenience in preparing the tables.

In principle one contestant is to be selected for each award (but if two or more contestants tie for a prize, then the prize is split instead selecting one from the tied contestants based on other considerations).

The question now is how to utilize the incomplete rank score matrices to determine the awardee(s) for each prize. There are a number of ways summarizing the incomplete rank score matrices and awardee(s) may be selected based on any of several summary statistics. We present several summary statistics for the Youden prize rank score matrix in Tables III, IV, V, VI, VII.

TABLE III

Sum of all Scores in Table I with
Missing Scores Replaced by Average Scores

C ₁	C ₂	C ₃	C ₄	C ₅	C ₆	C ₇
80	86.5	61	58	85	43.5	90

TABLE IV

Sum of Modified Scores (5 points for a first place vote, 4 points for a second place vote, ..., 0 points for a sixth or seventh place vote and missing scores replaced by average scores for referees 16 through 24)

C_1	C_2	C_3	C_4	C_5	C_6	C_7
56.62	64.42	40.62	38.7	61.08	28.28	69.28

TABLE V

Sum of Modified Scores (3 points for a first place vote, 2 points for a second place vote, 1 point for a third place vote, 0 point for others and missing scores replaced by average score for referees 23 and 24)

C_1	C_2	C_3	C_4	C_5	C_6	C_7
21.7	26.7	12.7	14.7	23.5	9.2	33.7

TABLE VI

Sum of Modified Scores (2 points for a first place vote, 1 point for a second place vote, 0 point for all others, and missing scores replaced by average score for referee 24)

C_1	C_2	C_3	C_4	C_5	C_6	C_7
9.17	14.17	6.17	8.17	10.17	8	19.17

TABLE VII

Frequency of the First Place Vote

C_1	C_2	C_3	C_4	C_5	C_6	C_7
3	3	1	3	4	2	8

From Tables III, IV, V, VI and VII we see that contender C_7 is obviously to be selected as winner of the Youden prize, even though Tables III and IV show that contestant C_2 is very close. We next look at the Wilcoxon prize rank score matrix of Table II, and again obtain several summary statistics (in Tables VIII, IX, X, XI, XII).

TABLE VIII

Sum of All Scores in Table II with missing Scores Replaced by Average Scores

C_1	C_2	C_3	C_4	C_5	C_6
69	71.5	59.5	76.5	55	67.5

TABLE IX

Sum of Modified Scores (4 points for a first place vote, 3 points for a second place vote, ..., 0 points for others and missing scores replaced by average scores for referees 17, 18 and 19)

C_1	C_2	C_3	C_4	C_5	C_6
32.67	35.93	24.33	41	23	33.67

TABLE X

Sum of Modified Scores (3 points for a first place vote, 2 points for a second place vote, 1 point for a third place vote and 0 points for all others)

C_1	C_2	C_3	C_4	C_5	C_6
20	21	12	22	13	23

TABLE XI

Sum of Modified Scores (2 points for a first place vote, 1 point for a second place vote and 0 points for all others)

C_1	C_2	C_3	C_4	C_5	C_6
11	8	6	14	10	14

TABLE XII

Frequency of the First Place Vote

C_1	C_2	C_3	C_4	C_5	C_6
3	3	1	5	2	5

In attempting to determine the awardee of the Wilcoxon prize, we now have a problem: the summary measures in Tables VIII - XII do not all lead to the same selection. While Tables VIII and IX indicate that C_4 should be selected and Table X shows

that all the contenders except C_3 and C_5 are very close with C_6 having a slight edge over others, Tables XI and XII clearly suggest that the Wilcoxon prize should be split between C_4 and C_6 . In order to resolve this problem, we must now face two

questions: "What do we mean by "the best contender"?", and "Given the definition of best contender, which of Tables VIII - XII should a selection procedure be based upon?"

DEFINITIONS AND PROCEDURES

Suppose that the number of contenders is k ($k = 2$ or 3 or 4 or ...) and that each expert ranks at least t ($1 \leq t \leq k$) contenders from best to worst. Denote the i th contender by C_i .

Let $\phi_{i\ell}$ denote the probability that contender C_i is rated as the $(k-\ell+1)$ st best, among C_1, \dots, C_k , by any expert. Define

$$\mu_i(t) = \sum_{\ell=k-t+1}^k (\ell + t - k) \phi_{i\ell}.$$

Call the contender associated with $\max(\mu_1(t), \dots, \mu_k(t))$ the best contender (by ranking) t-out-of-k, and denote that contender as $C\text{-best}(t)$. (It is, of course, possible that different contenders are $C\text{-best}(t)$ for different values of t , a fact related to the so-called "voting paradox". Hence we should not be surprised if different values of t lead to different selections by our procedures below.)

The selection procedure $R(t)$ for finding the $C\text{-best}(t)$ contender is: Assign scores $t, t-1, \dots, 2, 1$ and $k-t$ 0's to the k contenders, using the rank score matrix of the n judges. (The higher the score, the better a contender is rated.) Denote by $R_{ji}(t)$ the score assigned to C_i by the j th referee. Let $V_i(t) = \sum_{j=1}^n R_{ji}(t)$, and select the contender with the largest of $V_1(t), \dots, V_k(t)$,

$$\max(V_1(t), V_2(t), \dots, V_k(t)),$$

as the best. If two or more tie either split the first place or select one based on other considerations (or break the tie by randomization). The first two options are recommended for practice. (The last option is required for theoretical development of selection procedures below.)

The Youden award rank score matrix leads to selection of C_7 as the best contender, regardless of the choice of t . As for the Wilcoxon award,

$$\max(V_1(5), V_2(5), \dots, V_6(5)) = V_4(5),$$

$$\max(V_1(4), V_2(4), \dots, V_6(4)) = V_4(4),$$

$$\max(V_1(3), V_2(3), \dots, V_6(3)) = V_6(3),$$

$$\max(V_1(2), V_2(2), \dots, V_6(2)) = V_6(2) = V_4(2),$$

$$\max(V_1(1), V_2(1), \dots, V_6(1)) = V_6(1) = V_4(1).$$

Thus either C_4 or C_6 or both are selected dependent on the value of t used (and/or

whether or not randomization is done). Since (as will be shown below) $t = 1$ is in a certain sense superior to the other possible choices of t , it is reasonable to select both C_4 and C_6 , and this was the actual decision reached.

MATHEMATICAL DETAILS; RELATIVE EFFICIENCY; CHOICE OF t

In the following we will assume that the best contender is the same regardless of the choice of t . (This assumption is needed because the choice of t , i.e. comparing $R(1), R(2), \dots, R(k)$, makes sense only when the best contender is not definition-specific (because if it is definition specific, so also must the procedure be definition-specific).)

Let $\mu_{[1]}(t) \leq \mu_{[2]}(t) \leq \dots \leq \mu_{[k]}(t)$ denote ordered unknown values of $\mu_1(t), \mu_2(t), \dots, \mu_k(t)$ and $\hat{\mu}_{(i)}(t)$ be the probability associated with $\mu_{[i]}(t)$. The contestant associated with $\mu_{[i]}(t)$ is unknown for each i and denoted by $C_{(i)}(t)$. The strength of a selection procedure is often measured by the probability of correct selection. If $V_{(i)}(t)$ denotes the statistic associated with $C_{(i)}(t)$, then correct selection (CS) means the event

$$V_{(k)}(t) = \max(V_1(t), \dots, V_k(t)).$$

If $P(\text{CS} | R(t)) \leq P(\text{CS} | R(t'))$ when we have n referees and k contenders, then procedure $R(t')$ should be preferred in this situation.

For notational convenience only, and without loss of generality, we assume that the k^{th} contestant is the best. Thus the statistic and parameters associated with C_k are simply $V_k(t)$ and $\phi_{k\ell}$.

We will now suppose that

$$\phi_{kk} \geq \phi_{k\ell} \text{ and } \phi_{kk} \geq \phi_{\ell'k}, \quad 1 \leq \ell, \ell' \leq k-1, \quad (1)$$

that is we assume that the probability that the best contestant is rated best by a referee is greater than the probability that he is rated as $(k-\ell+1)^{\text{st}}$ best ($1 \leq \ell \leq k-1$) and is greater than the probability that another contestant is rated best.

Let n, k, t , and λ^* , $1 < \lambda^* < \infty$, be fixed and suppose (1) satisfies

$$\phi_{kk} \geq \lambda^* \phi_{k\ell} \text{ and } \phi_{kk} \geq \lambda^* \phi_{\ell'k}, \quad 1 \leq \ell, \ell' \leq k-1. \quad (2)$$

Then for $t \geq 2$

$$\inf_{\phi_{ij}} P[CS|\phi_{ij}, R(t)] \leq P[CS|R(t), \phi_{kk} = \lambda^* \phi_{k\ell} = \lambda^* \phi_{\ell'k}, \phi_{\ell\ell'} = \phi_{\ell'\ell}, 1 \leq \ell, \ell' \leq k-1] \quad (3)$$

and for $t = 1$

$$\inf_{\phi_{ij}} P[CS|\phi_{ij}, R(1)] = P[CS|R(1), \phi_{kk} = \lambda^* \phi_{\ell k}, 1 \leq \ell \leq k-1]. \quad (4)$$

In fact $P[CS|\phi_{ij}, R(1)]$ is a function of only $\phi_{kk}, \phi_{(k-1)k}, \dots, \phi_{2k},$ and ϕ_{1k} , and a proof of (4) is given by Kesten and Morse⁽⁵⁾. (Note that without the randomization the equality (4) is true only asymptotically, since as $n \rightarrow \infty$, the probability that randomization is required goes to zero. For a more detailed discussion, see Lee⁽⁷⁾.)

For large n an approximation to the right hand side of (3) and (4) is given by

$$\int_{-\infty}^{\infty} \frac{1}{2} \left(\frac{z}{a(\lambda^*)} + \frac{n^{1/2} t(\lambda^*-1)(2k-t-1)b(\lambda^*)}{2(k+\lambda^*-1)(k-1)\tau(\lambda^*)a(\lambda^*)} \right) d\tilde{z}(z), \quad (5)$$

where

$$\tilde{z}(x) = \int_{-\infty}^x (2\pi)^{-1/2} \exp(-x^2/2) dx,$$

$$a(\lambda^*) = \left\{ \frac{\tau^2(\lambda^*) - \gamma(\lambda^*)}{\gamma(\lambda^*)} \right\}^{1/2},$$

$$b(\lambda^*) = \{1 + a^2(\lambda^*)\}^{1/2},$$

$$\tau^2(\lambda^*) = \text{Var}\{n^{-1/2}(V_k(t) - V_1(t))\},$$

and

$$\gamma(\lambda^*) = \text{Cov}\{n^{-1/2}(V_k(t) - V_1(t)), n^{-1/2}(V_k(t) - V_2(t))\}.$$

Equation (5) can be computed numerically using Gaussian quadrature. Approximation by (5) is fairly reliable, and was off by less than 0.01 for the cases studied.

We can compare the selection procedures $R(t)$ by computing (5) for each t with fixed n, k , and λ^* . For example, see Table XIII.

TABLE XIII

P[CS] Comparisons

n	k	λ^*	$P[CS R(k)]$	$P[CS R(1)]$
30	5	2.0	0.731	0.787
30	6	2.0	0.559	0.728
30	7	2.0	0.470	0.673

Instead of computing $P[CS(R(t))]$ to compare $R(t)$'s for given n , k , and λ^* , however, we equate (5) to a given P^* ($1/k < P^* < 1$) and solve the smallest n needed to satisfy the equation. Denote that n by $n_{k,t}(\lambda^*, P^*)$. The ratio $n_{k,t}(\lambda^*, P^*)/n_{k,t'}(\lambda^*, P^*)$,

$1 \leq t \neq t' \leq k$, is called the relative efficiency of $R(t')$ with respect to $R(t)$, denoted by $\text{Eff}[R(t'), R(t)]$. If $\text{Eff}[R(t'), R(t)] \geq 1$, then procedure $R(t')$ is at least as efficient as $R(t)$. Of particular interest is $\text{Eff}[R(1), R(t)]$. Since $\text{Eff}[R(1), R(t)]$ requires a computation for each combination of (k, λ^*, P^*) , we instead compute and obtain

$$\lim_{\lambda^* \rightarrow 1} \text{Eff}[R(1), R(t)] = \frac{t+1}{3} \frac{(k-1)(4tk+2k-3t^2-3t)}{t(2k-t-1)^2}. \quad (6)$$

If $t = k$, $\lim_{\lambda^* \rightarrow 1} \text{Eff}[R(1), R(t)] = (k+1)/3$. In our Wilcoxon prize example with $k = 6$,

(6) is given in Table XIV. We thus see

TABLE XIV

t	2	3	4	5	6
$\lim_{\lambda^* \rightarrow 1} \text{Eff}[R(1), R(t)]$	1.30	1.67	2.04	2.33	2.33

that $R(1)$ is the most efficient procedure.

Note that whether inequality (3) is strict or not, the conclusion obtained does not change. If inequality (3) is strict, then the efficiency given by (6) is a lower bound for $\lim_{\lambda^* \rightarrow 1} \text{Eff}[R(1), R(t)]$. We conjecture, however, that inequality (3) is not strict.

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Because of the present economic and sociologic environment, there is an increasing awareness and subsequent stress in industry of providing management with the most accurate and timely view of the state of the quality system. As an aid to proper decisions on the acceptability of the quality of design as well as quality of conformance, it is frequently desirable to know the underlying distribution of pertinent quality characteristics. Although there has been much work recently to improve the application of (univariate) non-normal forms to industrial problems, these techniques do not consider the multivariate structure prevalent in many situations.

This paper will discuss the availability of multivariate non-normal distributional techniques and examine their merits within an industrial environment.

INTRODUCTION

Beginning in the mid-sixties, there has been a rapidly increasing trend in consumer awareness and subsequently in demands for "bigger and better" products. This growing consumerism has, in turn, motivated politicians to introduce and pass legislation and regulations which impact all areas of manufacturing and service. Since some of these political rules may run counter to popular (individual) opinion, the manufacturer may be caught between conflicting goals. Yet he must do his best to satisfy both, often treading a fine line between politically and commercially acceptable.

A basic but global example of this phenomena can be seen in the changes wrought by the various safety regulations. These regulations, aimed to protect the lowest common denominator (often from himself), can require extensive processing changes and/or additions to the product. This, in turn, increases the cost which may be more undesirable to the consumer.

Thus, the manufacturer must gather in a timely, efficient and effective manner information on the status of the product/process. This endeavor is complicated by the fact that a product/process rarely has only one characteristic of interest. Even if these multiple characteristics have all the "nice" properties (normality, mutually independent), application of traditional quality control and univariate data analysis techniques tend to be conservative and therefore cost ineffective when applied to these multiple variable situations.

The government is also finding itself in increasing similar predicaments. With every new governmental regulation and standard, new regulatory agencies must be formed or existing agencies expanded in order to ascertain the compliance of industry to the standard and subsequently to enforce the regulation when necessary. Because of budgetary and political pressures, the agencies want to gather the requisite information in a timely, efficient and effective manner.

Although the agency often can (and does) minimize the in-house cost of data collection by requiring the manufacturer to periodically gather and report information on a specified sample, it is realized that this cost is ultimately born by the consumer via taxpayer. (Note that we have come fully round the circle back to the consumer.)

The scenario is further complicated by the overlapping responsibilities of several semi-autonomous agencies. For example, on December 31, 1974, the Environmental Protection Agency (EPA) issued proposed regulations concerning the selective enforcement audit of end-of-line automotive emissions. This proposal specified an attribute sampling plan with a 10% AQL to be applied to each of the three major emissions constituents: hydrocarbons (HC), carbon monoxide (CO), and oxides of nitrogen (NOx). If this regulation was implemented as proposed, an audit would be successfully passed if each individual characteristic separately passes. If these vehicles were scheduled to be sold in California, they would also have been subjected to the California Air Resources

Board's end-of-line emissions audit which required at least 10% of the vehicles tested to be under the standards on all three major constituents.

Both of these audits have the objective of assuring that vehicles being produced satisfy, at the end of the assembly line, the standards to which they were certified. Yet a manufacturer could have successfully passed one audit without gaining any assurance that he could pass the other audit.* [GRU 2] Additionally, these audit plans did not utilize the variables nature of emissions' measurements nor acknowledge the fact that these measurements are nontrivially correlated.

An "obvious" approach for any of the above situations is to utilize a variables sampling plan based on an appropriate non-normal multivariate continuous distribution. The problem, then, becomes to determine which sampling methodology should be utilized and how should this methodology be implemented within the industrial environment.

MULTIVARIATE ANALYSIS

In a broad yet actual sense, multivariate analysis encompasses practically the whole of statistical theory since any single sample can be considered as a special case of the multiple variate case in which the individual variables are independent. Also, in "traditionally" univariate problems, such as the test of equality of two means by the student T statistic, the primary idea (of multivariate analysis) of independence and the complementary idea of dependence is required.

Yet most people view multivariate analysis in a narrower sense as that "branch of statistics dealing with the summarization, representation and interpretation of data sampled from populations where the variable elements yield measures of more than one characteristic" [KRA 1]. Examination of the whole field of multivariate analysis yields two primary features:

- o Consideration of a set $X = \{x_1, \dots, x_n\}$ where each x_i is an element of the same p space (i.e., consists of p variables).
- o The variates are dependent among themselves and must be considered together; an individual (or group of) variate cannot be isolated and considered independently.

The need to identify the dependence and/or interdependence relationships in a set of variates has resulted in five general categories of multivariate analysis.

- o Factor Analysis
- o Component Analysis
- o Discriminant and Classification Analysis
- o General Linear Multivariate Models
- o Distribution Analysis

The history of multivariate analysis is usually taken to have begun with the works of Francis Galton. Although the bivariate normal distribution has been studied throughout the nineteenth century, interest in multivariate analysis remained relatively dormant until it was stimulated by Galton. As early as 1889 he was applying the mathematics of the bivariate normal to studies of generic inheritance. He did not introduce any new forms of joint distributions himself, but he developed the idea of correlation and regression as expressions of linear relatedness of two variables and focused attention on the need for greater knowledge of possible forms of multivariate distributions. Besides being a pioneer of multivariate statistics, Galton is considered to be the founder of trait and factor psychology for which this methodology is required.

Subsequent development was channeled primarily by this type of use as well as by computational capabilities. The main emphasis was on non-engineering type problems (e.g., in biometrics, education, agriculture, sociology, psychology, etc). An underlying multinormal distribution was assumed by most investigations. This should not be surprising do to the complexity of multivariate forms and the fact that most calculations at this time were performed manually.

As an indication of the impact of this focusing of research to essentially the first four categories above, less than 7.5% of the entries in the extensive bibliography of

*Although the California Standards are presently lower than the corresponding Federal Standard, the statutory limits are the same. Thus the audits can be compared, assuming the same standards.

multivariate statistical analysis by Anderson, Gupta, and Styan [AND 2] deal with non-normal multivariate forms and analysis. Most of the entries dealing with these matters are highly specific and limited in application. In fact, the number of engineering applications, whether multinormal or non-normal are very limited. For example, less than a dozen Quality Control oriented papers can be found in the multivariate literature.

This seeming lack of interest in distributional analysis is unfortunate since although the engineering sciences can utilize elements of the first four categories above, it requires distributional analysis techniques.

Distributional Analysis

Any examination of available multivariate distribution analysis will show that the dominance of the multinormal distribution among multivariate distributions is more marked than that of the normal among univariate distributions. Because of this preponderance of literature on the multinormal, approaches in describing its distributional form are many and diverse. One of the more straightforward descriptions is that a set of random variables X_1, \dots, X_m have a joint multinormal distribution if their joint probability density function can be written in the form

$$P_X(X_1, \dots, X_m) = C \cdot \exp [-(\text{positive definite quadratic form in } X_1, \dots, X_m)] \quad (1)$$

with C an appropriate constant. If the exponent is written as $-\frac{1}{2}(X - \xi)' A(X - \xi)$ where A is a real symmetric positive definite matrix, then C must be a function of ξ and A and, in fact

$$C = (2\pi)^{-(1/2)m} |V|^{-1/2}$$

where $V = A^{-1}$ is the variance-covariance (dispersion) matrix of X. Therefore (1) can be written as

$$P_X(X, \dots, X_m) = (2\pi)^{-(1/2)m} |V|^{-1/2} \exp \{-(1/2)(X - \xi)' V^{-1}(X - \xi)\} \quad (2)$$

which is the "standard" multinormal form where V has the meaning given above and $\xi = E(X)$.

If A is only positive semi-definite (i.e. $|A| = 0$), the joint distribution of X_1, \dots, X_m is called multinormal.

Because of its form (1), the multinormal has the property that if any subset of variables is eliminated (by integration) the remaining variables have a joint density function of the same form.

In addition to these properties, the multinormal shares with the univariate normal the characteristic that the (joint) distribution of any linear function of X's will be a (singular or nonsingular) multinormal distribution.

Full accounts of the history and development of the multinormal can be found to some extent in virtually all books on multivariate statistics. Most notable are those written by Anderson [AND 1], Dempster [DEM 1], Kendall [KEN 1] and Johnson and Kotz [JOH 1].

As in the univariate case, research in the multinormal distribution has generated "spin off" research into multivariate sampling distributions analogous to the univariate t, χ^2 (or gamma) and F (or beta). That is given a random sample of size n from an m-variate multinormal population, the observations can be represented by n independent vectors $x_i = (x_{i1}, \dots, x_{im})$ with probability density function given in (2). The maximum likelihood estimators of the elements of V are the corresponding elements of $n^{-1}S$ where

$$s_{ij} = \sum_{i=1}^n (x_{ij} - \bar{x}_{.j})(x_{ik} - \bar{x}_{.k})$$

and

$$\bar{x}_{.j} = \frac{1}{n} \sum_{i=1}^n x_{ij}$$

For the univariate case ($m=1$) the distribution of $S = s_{11}$ is just χ^2 with $v = n-1$ degrees of freedom. Thus the joint distribution of S is regarded as the generalization of the univariate χ^2 (or gamma) distribution. It should be noted that this is not a multivariate gamma distribution since these have all marginal distributions of the gamma type while for $j \neq k$, s_{jk} does not necessarily have a distribution of the gamma type.

The joint distribution of the variance-covariances for m normal variates was developed by Wishart [WIS 1] in 1928 and is called a Wishart distribution. Fisher had previously (1917) obtained similar results from the bivariate case. Although latent in Wishart's work, the characteristic that the dispersion matrix was the natural extension of the variance in univariate theory to the multivariate case was brought out by Wilks in 1932. Consequently one line of development has been the study of ratios of matrices of the dispersion type, this being the multivariate analogue of the t distribution, F distribution, etc.

As before, suppose $X = (x_1, \dots, x_m)$ is multinormal with mean vector ξ and dispersion matrix V . Let S, S^* be independent m Wishart matrices also with the dispersion matrix V , based on n, n^* degrees of freedom, respectively. Then if T is a $m \times m$ matrix such that $TT' = S$, natural candidates for the multivariate analogue of t and F are

$$\tilde{t} = T^{-1} (x - \xi) \quad (3)$$

$$\tilde{F} = T^{-1} S^* T^{-1} \quad (4)$$

Although (3) can be shown to be equivalent to the general multivariate T distribution it is by no means the only candidate. Similarly with (4) and the multivariate beta.

Additional generalized multivariate beta distributions have been described by Waal [WAA 1], Mitra [MIT 1], Khatri [KHA 1], Krishnaiah [KRI 2], and Bennet [BEN 1] to reference a few.

This same type of multiplicity of forms is also evident for the multivariate gamma distributions. For example, see Sarmanov [SAR 1], Eagleson [EAG 1], Moran [MOR 1, 2], Bose [BOS 1] or Krishnaiah et al [KRI 3].

Considering all these different forms each stating to be the generalized multivariate beta/gamma, it is natural to question if there is a general "generalized" multivariate beta/gamma. Since the univariate Pearson family of distributions encompass both the univariate beta and gamma distributions (cf Gruska, Mirkhani and Lamberson [GRU 1]), a multivariate equivalent of this family would be a reasonable starting place.

Extension of the Pearson family to the bivariate case has been exhaustively described by Van Uven [UVE 1, 2] and reported by Johnson and Kotz [JOH 1]. The generalization is accomplished by replacing the differential equation for the univariate family

$$\frac{1}{y} \frac{dy}{dx} = \frac{a + x}{c_0 + c_1 x + c_2 x^2} \quad (16)$$

by the pair of partial differential equations

$$\frac{\partial \log y}{\partial x_j} = \frac{L_j(x_1, x_2)}{Q_j(x_1, x_2)} \quad (j = 1, 2) \quad (17)$$

where L_j and Q_j are linear and quadratic functions respectively. By equating the two different expressions for $\partial^2 \log y / \partial x_1 \partial x_2$, it can be seen that the L_j 's and Q_j 's cannot be chosen in a completely arbitrary manner but must satisfy the relationship

$$Q_1^{-2} Q_1 \frac{\partial L_1}{\partial x_2} - L_1 \frac{\partial Q_1}{\partial x_2} = Q_2^{-2} Q_2 \frac{\partial L_2}{\partial x_1} - L_2 \frac{\partial Q_2}{\partial x_1}$$

The marginal distributions of these joint density functions can be represented by Pearson type curves and it is possible to fit the parameters of these curves by the method of moments.

In fact, none of the multivariate density functions--including those not described here such as the noncentral versions of the multivariate χ^2 , F, beta, or gamma, series expansions etc.--are feasible choices for a general (wide applicability) non-normal multivariate distribution. The reasons for this are primarily

- a) functional complexity requiring extensive numerical calculations not only for parameter determination but also for evaluating the corresponding distribution function.
- b) unlike the multinormal, it is not possible to replace a pair of correlated variables by a pair of independent ones (using a transformation corresponding to a rotation of axes) in order to simplify the analysis.

The first problem (a) may be minimized by considering multivariate distribution functions while (b) may be handled by multivariate translation systems.

One univariate distribution function which is used extensively in the areas of reliability and stress/fatigue analysis is the exponential distribution

$$F(x) = 1 - \exp(-x/\theta_0), \quad (x > 0; \theta_0 > 0) \quad (4)$$

Bivariate analogues of this form has been developed by Nagao and Kadayama [NAG 1], Gumbel [GUM 1], Moran [MOR 2] and Freund [FRE 2]. Weinman [WEI 1] extended Freund's bivariate exponential distribution to a multivariate exponential distribution by considering the reliability of a system having m identical components with time to failure X_1, \dots, X_m , each an exponential distribution of form (4).

Since the distribution of $X^{1/C}$ is Weibull if X is an exponential, multivariate Weibull distributions can be constructed as the joint distributions of $X_1^{1/C}, \dots, X_m^{1/C}$ where X_1, \dots, X_m have a joint multivariate exponential distribution.

The multivariate Weibull distribution can also be approached through the extreme value distributions. The extreme value distributions are obtained as limiting distributions of the greatest (or least) values in random samples of increasing size. Extension of this concept to the bivariate case (i.e. considering the joint cumulative distribution function of X_{\max} and Y_{\max}) have been obtained by Geffroy [GEF 2], Gumbel [GUM 4], Sibuya [SIB 1], and Oliveira [OLI 1]. Unfortunately, a general multivariate extreme value distribution has not been developed.

Another useful univariate distribution function is the Burr distribution (see Burr [BUR 1], Gruska, et al [GRU 1]) which has the form

$$F(x) = 1 - (1 + x^c)^{-k} \quad (c, k > 0; x > 0). \quad (5)$$

The joint (unconditional) density function of a multivariate Burr is (Takahasi [TAK 1])

$$p(x) = \frac{\Gamma(k+m)}{\Gamma(k)} \left(1 + \sum_{j=1}^m d_j x_j^c \right)^{-(k+m)} \prod_{j=1}^m \frac{c_j}{x_j} \alpha_j c_j x_j^{c_j-1} \quad (6)$$

Takahasi also showed that any subset of the X 's have a joint density function of this same form (6), with appropriate changes in the parameters!

One of the disappointments in collecting the above information is that the literature search has not uncovered any quality control methodology based on non-normal multivariate distributions. Any quality control methods reported relied on the characteristics of the multinormal distribution.

One major advantage the multinormal distribution has over its non-normal brethren is model simplification ability (b above). This has assisted researchers in developing many useful tools based on the multinormal. In order to utilize this wealth of techniques, it would be natural to attempt to transform a general multivariate population into a multinormal population. Consequently, research on this subject can follow one of three distinct paths: (1) development of requisite techniques for a specific multivariate density function(s); (2) development of techniques for a specific multivariate distribution function(s); (3) development of methods to translate non-normal multivariate data into multinormal data and development/extension of multinormal QC techniques. Of these, the third seems most tractable from a computational and implementation standpoint.

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Public Health Service
Department of Health, Education, and Welfare

What has the Quality Manager in common with good reporters and good intelligence operatives? He has a need to know. He has specific requirements for information. Like a reporter or an intelligence operative, he needs a reliable source of information. The manager of quality, however, should have an advantage over the reporter and the intelligence operative simply because his company has developed a fine quality philosophy, a good set of quality objectives, practical operational manuals replete with reporting and feedback mechanisms, an excellent set of specifications for products and processes, and the most sophisticated testing and sampling protocols required to do the job, yet with all of these techniques, the manager of quality finds it necessary to evaluate the quality program periodically to assure himself and his management that the right things are being done, and that they are being done properly. How does the manager get his job done? How does he use the questions - Who? What? Where? When? Why? and How? to help him. Today, I am sharing the session with Bill Golomski, who will be discussing a similar subject in regard to consulting firms. I can assure you that we did not collaborate on selecting topics for this presentation, nor have we shared our speeches prior to the deadline for publication in the Annual Technical Conference transactions. Both papers relate to aspects of communication which need to be highly developed by the Quality Manager, or by the user of external consulting services.

Let's review a few concepts before I launch into my socratic process. We have made assumptions that quality documents have been prepared and quality systems are in place within the company. A company may be a manufacturer of goods. It may be a purveyor of services, or, as in the case of Government, it may be a non-profit publicly owned corporation which is in the business of regulation or purveying services. The discussion today applies to all of these enterprises. In each enterprise, there is a balance of resources which is applied against a task or program. In each, the dollar is a common factor. In each of the enterprises as well, there is a determination of success or failure based upon the delivery of goods or services within a specified time period. In each, too, there is an assessment of the quality of output judged against specifications. It is necessary to over-simplify in order to cover the subject within the time allotted. Therefore, I have restricted my comments today to a discussion of "Executive Techniques for Snow Removal" in the management of quality. You will agree that there are aspects of quality management throughout all phases of the operation of an enterprise, yet all enterprises do not have staffs dedicated to the management of quality. What is being said here today in regard to the management of a quality operation may be applied within any enterprise which is interested in improving its operation.

Let's find out a little about ourselves. Let us ask ourselves - How have we designed our jobs? What qualifications must our employees have in order to do the jobs? Where can we find people with those qualifications? What do we have to do to qualify them? Who will train them? Who will supervise them? What is the quality of our supervisory talent? Where do we get our supervisors? After we have answered these questions, it is possible to look more specifically at the management of quality in terms of Who? What? Where? When? Why? and How? What do

you expect of your employees? How can you optimize their performance? Have you provided them with proper tools, proper training, proper supervision, and appropriate follow-up? Have you challenged them? Have you made them aware of the responsibility that they have for accomplishing the job? Have you encouraged them to think about what they are doing, and how what they are doing relates to the goals of the company? Do you encourage them to furnish honest, forthright reports, regardless of the consequences, or do you merely want them to give you the good news? Do you know their individual strengths and weaknesses? Do you check up on them to see that their reports are complete and accurate? Do you require certification or qualification of your personnel? Do you perform checks on their performance to assure that they know what they are to do, that they are doing the right thing, and that they are doing it properly? To whom have you delegated responsibility for supervision? Have you informed your employees and your supervisors what the checks and balances are? When procedures will be executed? And why? Have you advised them of the consequences to the company, to your department, and to them for failure to comply with the rules and regulations, specifications, SOP's, etc.? Have you assured that the Labor Management Agreement reflects your requirements for personnel? Is the labor organization attuned to your requirements? What do they do to assure compliance?

Quality Assurance functions, of course, vary among companies and among departments within a single company. Some quality functions are scattered among diverse departments: for example, Research and Development; Quality Control or Quality Assurance; Purchasing; Distribution, and perhaps others. What have you done to assure that the quality objectives of the company are translated into action within all other departments having quality functions? What have you done to assure that the quality requirements of the company are followed? Who in those other departments has quality responsibilities? To Whom do they report? How do you assure that the quality objectives are met? Certainly, the quality function must be managed, but it is not entirely clear to all managers and all companies that quality is all pervasive. It is necessary for the manager of a quality function to assert himself, to assure that his boss knows that the new plant being built down the road meets the requirements for a quality environment in which a quality product is to be made. He needs to know that the proper equipment is being used to produce that product. He needs input to the training programs, and even the hiring practices to assure that the proper people are selected for the job. All of these activities are preventive in nature. They are designed to minimize the impact of defective personnel, defective product, defective equipment, defective processes, procedures, etc. Certainly, prevention activities have costs associated with them. How do you compare your costs of prevention with the other costs of quality? How do you allot your funds in one area vs. another? What should your payoff be? Where will you realize the profit or the loss? It seems essential that one have at his disposal a system for determining quality costs. It seems equally important to have cost centers built into the accounting system which will capture these costs. What can the Quality Manager do to get such accounting systems installed? How can he justify the existence of such a system? What advantage would it have to company management?

Such systems may improve the ability of the Quality Manager to determine accurately the costs of quality. Paralleling this system, and perhaps integrated into it, may be an audit system which helps to answer the questions - What is the organization doing vs. what should the organization be doing visa-vis quality management? What is the status of the quality control system? What are the results of quality control tests? What is the quality of product or service? What provisions are there for making alterations when defective systems are detected? How often are systematic reviews made of the entire operation for effectiveness? What are the most likely areas for performance or cost improvement? The Quality Manager must answer these questions because in a sense, answers to these questions and questions like them, justify his existence.

The Quality Manager must learn to ask the hard questions - questions designed to elicit a meaningful response about a product, a process, a test, a procedure, a report, or any other aspect of the quality assurance operation. He should not ask the technician - Did you do the test? - because he would get a simple non-definitive response of either "Yes" or "No." It would be much better for him to ask the question - What test did you perform? What method did you use? How did you conduct the test? - to elicit a specific response to the question. The manager may further ask, incorrectly - Was the test within specifications? The answer may be a non-definitive "Yes" or "No." It would be much better for him to ask - What were the test results? How did the results deviate from the standard or the specification value? Who performed the check analysis? I think you realize that snow removal techniques are simple means to get specific answers to questions which enable the Manager to learn or to obtain specific information about an operation. The Manager holds the key. If he asks a question that is not designed to elicit the response, he shows himself. Employees may also learn very quickly that if the Manager does not ask the right question, they do not have to be very precise in their response, and they may tend to give vague answers, non-specific answers to the questions. They learn very quickly how to snow their boss.

The Quality Manager must assure himself that his subordinates are doing their jobs effectively. His success or failure rides upon his ability to assess the situation to determine that the right things are being done and that they are being done properly.

LCS 300:10:000

WHAT TO EXPECT FROM AN EXTERNAL CONSULTING FIRM

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There are efficient ways to work with consultants and excellent ways to get the most out of consultants when you have fuzzy objectives.

The problem in many organizations is that it is considered a sign of weakness to admit that assistance is needed internally. To suggest that an external consultant is needed is even worse.

Organizations use consultants as:

1. Sources of information.
2. Designers of systems and products.
3. Temporary bodies for hire.
4. Experts to solve problems or as sounding boards for ideas.

Marketing research and patent searches are typical examples of using others for getting information. Simple survey work can be put out on a bid basis. Specialized depth interviewing or literature search is best done by those who specialize in it.

Quality Control work is often in the system design area. It requires more than someone who has worked in the field for years. You also need the ability to establish rapport with others quickly. It requires creative ability to design a system that fits the organization, rather than apply one that worked elsewhere, but may not apply.

An external consultant should:

1. Require you to state the study objectives and time of completion clearly.
2. Require you to "condition" the organization for your arrival unless "surprise" is the consulting strategy.
3. Use talent in the organization to assist in planning the details of the study, if appropriate.
4. Give periodic reports of findings during the course of the study. Perhaps some can be implemented without waiting for the study to be completed.
5. Report on uncooperating people who were supposed to cooperate; but he should give more than a modest effort to obtain cooperation first.
6. To report on problems or potential "problems" created by the consultant.
7. Submit a report which addresses itself to the objectives of the study.
8. To make sure that systems, practices and methods recommended are practical and implementable.
9. To assist in implementing if that is part of the contract.
10. To clearly state the fee schedule, expenses likely to be incorrect, an upper limit for the entire project, and how and when invoices will be submitted, and the terms of payment.
11. To give references, but not copies of reports done for others.

Don't expect a consultant to have experience in your industry. It isn't that essential. The important thing is to have worked successfully on problems such as you are facing.

Expect a consultant to tell you who in the firm will be working on your project, what their backgrounds are, and the approximate number of days each person will spend on the job.

Don't expect a consultant to sign the standard R&D agreement, if he is designing a sampling plan. This is an unfair limitation of the consultant's ability to build a professional practice.

Some consultants require a penalty for aborting a project. Try to get this provision removed, unless you have persuaded the consultant to enlarge his staff for your benefit.

Determine the number of copies of the report that you will get and state whether or not a special presentation on the results is to be given. If more are required, expect to pay for them.

Fees today range from \$150-\$200/day for retired people who are trying to keep from being bored or to supplement their income to \$350/day for younger professionals to \$500/day for experienced consultants to \$750/day principals to \$1500/day for those with rare specialized knowledge.

Training is usually at \$1000-\$2000/day for groups, if unique materials are to be prepared. A few lesser-equipped consultants will use the standard fee schedule given previously.

Consultants are in a peculiar position. They are brought in to solve problems and to make you stronger for having been there. Beware of those who want long contracts and large retainers. This might be needed, but it might be self-serving.

Consultants must be candid, and this may hurt. Make sure that they aren't destructive. Consultants should be articulate in their written reports and in their work. They must be able to sell concepts and ideas.

LCS 331:70:000

A TOTAL QUALITY CONTROL SYSTEM FOR FOOD PRODUCTION IN HOSPITALS

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INTRODUCTION

Food and the cost of operating a hospital food service has become a major expense for hospitals today. Of the amount spent by a hospital on the food service, approximately one-fourth of this is spent on incoming raw materials or food. Although quality control presently exists in some hospitals in the form of standardized recipes, standards, specifications, guides, etc., they lack a well-defined quality control program to insure that meals are served into which quality is designed, produced, and maintained at the most economical costs which allow for full patient satisfaction. The fulfillment of this total quality control concept requires the accomplishment of the four jobs of quality control: (1) new design control, (2) incoming material control, (3) food production control, and (4) special process studies. These jobs of quality control are achieved by (a) setting standards, (b) appraising conformance, (c) taking corrective action, and (d) planning for improvement.

The following paper presents a description of the jobs of quality control as proposed for implementation. Much more detailed work than can be shown in this paper is in the process of being developed, but food production control is the main emphasis for this paper. A proposed organization for quality control is also presented.

NEW DESIGN CONTROL

When one thinks of design, he usually envisions some part, sub-assembly, or complete system that will be blueprinted for production. Similarly, in a food service environment, the design for production is in the form of a written menu instead of a blueprint. At first glance, it appears that this is a problem for dietetics and does not involve anyone in the quality control department. However, several reasons necessitate that quality control be involved in developing new menus from initial menu development through production.

The first and most important case for quality to be involved in menu writing is to set the standards both for the menus themselves and for the raw materials. Since the quality control department has the responsibility of appraising conformance to standards, it is important that the standards are such that appraisal is both possible and economical. If a new menu requires the purchase of a raw material for which standards have not been established, then these must be determined. If a vendor is involved, then acceptance procedures and vendor certification possibilities need to be explored. Production of the new menu may require new measuring instruments to determine conformance to standards. The quality control department would be best suited for determining which measuring instruments are needed, or providing alternate standards which eliminate the need for this equipment.

A second reason for including the quality control department in menu writing concerns statistics. The need for the generation of new menus can be the result of several factors, but one of the more common is patient desires. The quality control personnel should be familiar with statistical procedures and can help provide statistically sound forms and procedures for evaluating patient preferences concerning food and food service.

Providing an organizational feedback loop for corrective action is the last argument for including quality control in the menu writing process. Since the quality control department is responsible for conformance to standards, it provides an organizational structure for providing management with deviation problems with the new menu. Management can then take the necessary corrective action, and the experience gained should help eliminate the same types of problems for future menus.

INCOMING MATERIAL CONTROL

It is usually true that a food product's ultimate quality is determined by the quality of the raw materials used to prepare the food product. Thus, quality control of incoming materials is very important. However, most hospitals receive such a large range of raw materials that if every single raw material, including those used in insignificant amounts, is to be subject to detailed examination and testing at frequent intervals, the cost will outweigh the advantages gained. It, therefore, follows that the dominant raw materials are selected for priority of attention and the selected materials are tested in relation to their contribution to product quality.

The VA has already established standards for most incoming raw materials.⁽¹⁾ Quality control's part is to design forms for inspection and establish the economical frequency of inspection. A quality audit should be made randomly to ensure the accuracy of inspection and that inspection is at the proper intervals.

Acceptance sampling procedures should be considered for some raw materials. There are two published sets of sampling plans for attribute sampling that should be considered. They are the MIL-STD-105D tables and the Dodge-Roming tables. One should become familiar with the philosophy toward protection before selecting a set of plans. Although not necessarily the best for a given application, the MIL-STD-105D is more widely recognized and used than the Dodge-Roming. The MIL-STD-414 tables can be used when variables sampling plans are needed. Variables sampling plans should be considered since smaller samples are needed when compared to attribute plans.

Although a large portion of the raw materials are purchased from government supply, some purchases involve vendors. Good vendor relations are important to insure the desired quality. A quality record should be kept for each vendor used and vendor certification needs to be encouraged. Certification by vendor of the quality of his product results in both commercial advantage to him and a minimum inspection by the hospital.

Most hospitals do not have adequate testing and measuring instruments. Most hospitals have scales and thermometers but, at a minimum, need a refractometer, brix hydrometer, and fat analyzer. Also, some hospitals do not have a testing laboratory for food, but do have laboratory facilities for microbiological testing.

FOOD PRODUCTION CONTROL

There is an old saying among quality control managers, "Quality cannot be inspected into the product." This means that quality control must exist as the food is being prepared. It also implies that the individuals who prepare the food are the most important determinants of quality. Management needs to stress the importance of quality and develop programs to reinforce good quality both in employee training programs and inspection techniques.

Quality is objectively measurable even though many food attributes are subjective. Quality is measured in terms of a product's chemical and physical attributes: flavor, texture, color, appearance, consistency, palatability, nutritional values, safety, ease of handling, convenience, and portion size. The administration of the techniques of pre-meal evaluation for taste control and control charts for portion size are being developed by Banik and Mathews.⁽²⁾

Before pre-meal evaluation can be implemented, a well defined program for sensory evaluation needs to be developed. This includes:

1. Developing a taste panel evaluation form
2. Procedure for setting up samples to be tested
3. Procedure for conducting taste panel and selection of panel or judges
4. Procedure for training taste panelists

Since taste is a much more subjective matter, being a combination of taste, smell, and feelings, training is a necessary first step to sensory evaluation. Judges learn how to handle food when tasting and to recognize and separate the various responses. They become acquainted with the terminology meaningful to the taste panel.

The pre-meal evaluation is a prime technique to stimulate employees interest and concern in consistently meeting quality standards over a long period of time. In this case, the pre-meal evaluation is being conducted in two different ways. First, all menu items at the noon and night meal need to be tasted to determine acceptability for patient consumption. Data is maintained on problem items. Five menu items are selected (on a random basis), placed on a table and tasted by designated individuals. The taste panel evaluation form (Figure 1) is filled out for these products, kept on file, statistics calculated and a p chart constructed. In this manner, statistical quality control can be maintained on food items, but does not take up a tremendous amount of time. Using this method, quality can be evaluated on new, problem, and regularly used menu items.

Portion control is not only related to quality (nutritional value) but also very closely connected with the administrative problems of purchasing, inventory, and production control. In anticipation of implementing a Computer-Assisted Food Management System, portion control became a more significant factor to be studied. The Computer-Assisted Food Management System would include:

1. Inventory Control System
2. Food Cost Accounting System
3. Food Production and Control System
4. Analysis of Patient Nutrient Intake
5. Menu Planning by Computer

The above system is based on standardized menus which are selected by the computer in a least cost manner while maintaining a designated variety in menu offerings. A linear programming model is used to accomplish this. This system is connected to inventory (automatically signals for purchases based on number and type of issues) and the cost accounting system. It then becomes evident that portion control is essential if the above system is to operate smoothly and efficiently.

A high variance in the weights of some menu items existed during an initial data collection period. The problem concerned items where there was a choice of using scoops or spoons for portioning. The proper use of scoops can eliminate shortages, prevent leftovers, and save time and money. However, the argument against scoops has been that scoops make the food look too institutionalized, a quality problem of appearance. Further investigation into the problem for possible solutions, including using automatic portioning equipment, should be conducted.

\bar{X} and R charts are going to be utilized on selected menus where problems of portioning exist. It is anticipated that they will not be necessary for a particular menu after the charts are brought into statistical control. It should be noted that control charts are very good tools for studying the variance of a process. They are also an

TASTE PANEL EVALUATION					
PRODUCT _____	RATING SCALE:				
CYCLE _____ WEEK _____	5-like extremely; 4-like moderately;				
DATE _____	3-neither like or dislike; 2-dislike moderately; 1-dislike extremely				
OVERALL APPEARANCE	1	2	3	4	5
Circle descriptive factors:					
Correct for product	Messy				
Appetizing	Signs of Deterioration				
Colorful					
OVERALL AROMA	1	2	3	4	5
Circle descriptive factors:					
Correct for product	Burnt or Scorched				
Aromatic	Dull				
Odorless	Putrid				
OVERALL TASTE	1	2	3	4	5
Circle descriptive factors:					
Correct for product	Too sweet				
Spicy	Too sour				
Strong	Too salty				
Tangy	Flat or Bland				
OVERALL TEXTURE OR CONSISTENCY	1	2	3	4	5
Circle descriptive factors:					
Correct for product	Tough				
Grainy	Tender				
Smooth	Thick				
Chewy	Thin				
Lumpy					
OVERALL ACCEPTABILITY: _____ ACCEPTABLE _____ UNACCEPTABLE					
COMMENTS: _____					

FIGURE 1. Taste Panel Evaluation Sheet

excellent tool for involving employees in quality control because variance can be seen by employees and feedback is immediate. Therefore, they will be used at different times for study or improvement projects. They may, in the future, find continuous use if new automatic portioning equipment is implemented.

A Patient Food Service Survey Questionnaire has been developed by the VA to be distributed to patients. Figure 2 shows a form developed by McLaren⁽³⁾ which has proved to be very useful for patient input. Information concerning items missing from trays, quality of items, and request for menu suggestions are solicited using the form. A space also is reserved for additional comments. To boost employee morale, favorable comments from patients are brought to their attention.

SPECIAL PROCESS STUDIES

This job of quality control is organized to handle special studies. For example, a study was performed to determine if one of five bakery items was significantly better than the others. Four of the items were from different vendors and the remaining item was from the hospital

COMMUNITY HOSPITAL OF INDIANAPOLIS, INC.

Time _____ Day _____ Date _____

PATIENT - FOOD SERVICE SURVEY

INTRODUCTION:

This survey is being conducted as part of a continuing effort to provide good food service. Your cooperation in completing this questionnaire will be most appreciated. If you wish, you may leave your name off, but please complete the rest of section 1.

In section 2 we are interested in learning your general opinion of our food service. For each topic, check one square to indicate the phrase that best describes your opinion of that aspect of the food service, and make any additional comments under each phrase.

1. Name _____ Room Number _____ Current Diet _____
Length of current hospital stay _____

2. SURVEY	<u>Very good</u>	<u>Good</u>	<u>Fair</u>	<u>Poor</u>	<u>Very Poor</u>
Hot food temperature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cold food temperature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Attractiveness of trays served	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Selection and variety of food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cleanliness of dishes, utensils, and trays	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Handling ease of utensils and dishes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quantity of food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality of service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality of food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Have you received all of the items marked on your menu? Yes _____
No _____ If no, what was missed and about how often? _____
4. Has someone from dietary visited you? Yes _____ No _____
5. What foods would you like to see on the menu that do not appear now? _____
6. What foods that do appear would you like more frequently? _____
7. What foods that do appear would you like less frequently? _____
8. ADDITIONAL COMMENTS: _____

FIGURE 2. Patient Food Service Survey

bakery. A ranked sum analysis of variance was suggested as the means of analysis. Many continual problems such as pre-portioned frozen meat versus having a meat shop fall into this job function. Special process studies are especially pertinent to the VA in relation to quality of convenience products since the VA is interested in obtaining and maintaining quality convenience products for patient use.

THE FOOD QUALITY CONTROL ORGANIZATION

Before the four jobs of food quality control can be accomplished in an integrated manner, an organizational structure needs to be meshed into the overall food production organization. The proposed organization should be a staff function reporting directly to the Chief of Dietetic Service. This is shown in Figure 3.

Unlike large organizations with at least one employee in each job of quality control, only two employees will be required. Since dietetic personnel presently spend time on quality functions, it is anticipated that, by reassignment of functions, only one additional employee will be needed--the quality manager. It is also expected that the savings resulting from implementing the jobs of quality control will more than offset the expense of the quality manager.

The success or failure of the quality control organization depends largely on the quality control manager. The most important qualification for the quality control manager is that he or she be a good administrator. A registered dietitian with a Masters Degree related to management, advanced training in quality control administration or experience in a quality control program would be preferred. A basic understanding of statistics and sampling tables is a must. A Certified Quality Engineer would also be a possibility. Another possibility is that a current staff dietitian working in administration be trained to develop and carry out a quality control program. The primary responsibilities of the Quality Control Dietitian would be the development of a quality control program that fits the needs of the institution, development of procedures for inspection techniques and data collection, determining statistical methods and sampling tables that are to be used, analyze data, followup, regular quality audits, and total communication with the Chief Dietitian.

The quality control technician should be a person with a B.S. degree and the ability to work well with the food production personnel. The primary responsibility of the technician would be to relieve the Quality Control Dietitian of routine quality control tasks, for example, the daily taste panels held in production, data collection and maintenance of control charts.

ACKNOWLEDGEMENTS

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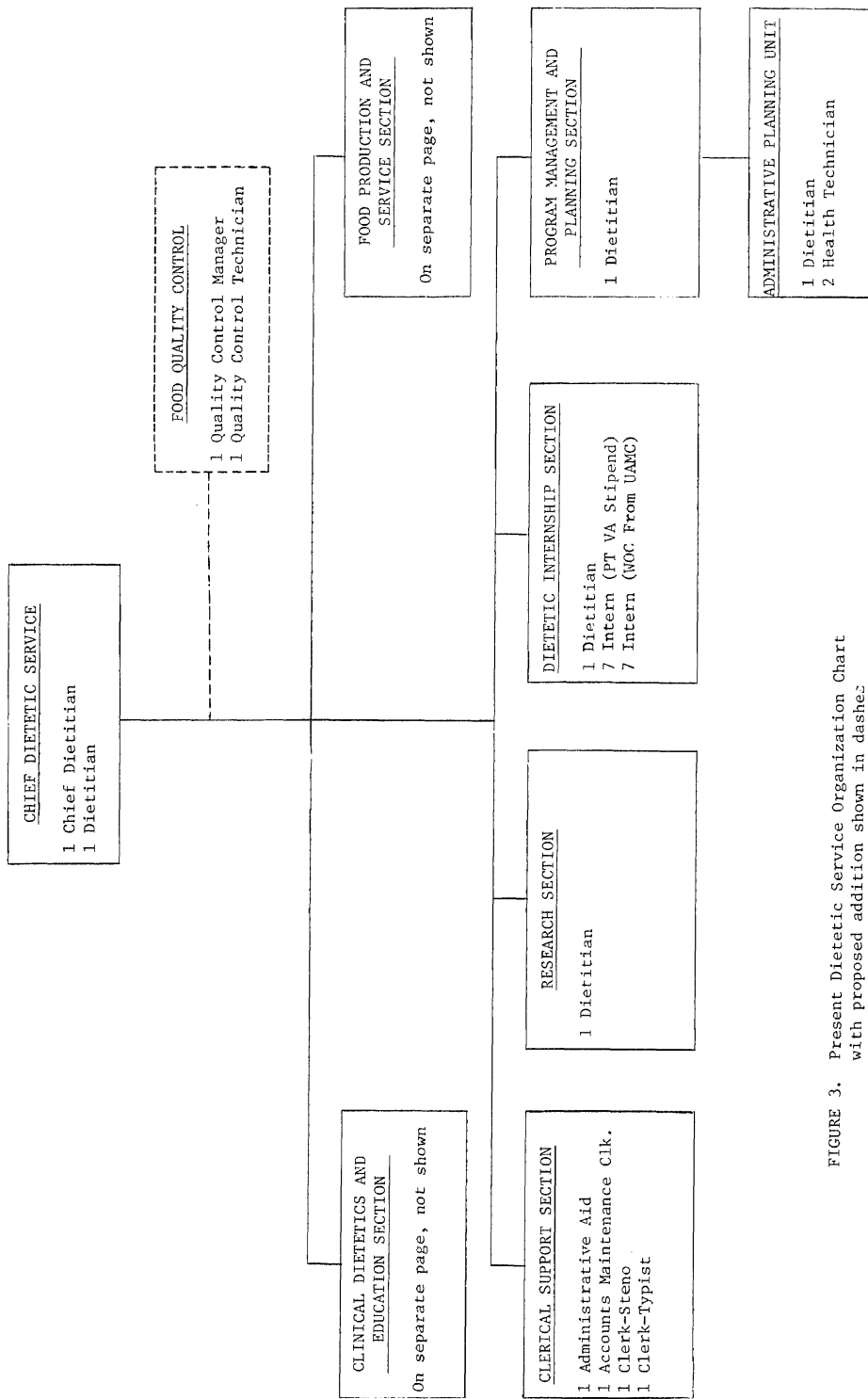


FIGURE 3. Present Dietetic Service Organization Chart with proposed addition shown in dashes

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LCS 300:10:870

A WEIBULL SHELF-LIFE MODEL FOR PHARMACEUTICALS

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INTRODUCTION

Much new statistical technology has been developed in the aerospace and defense industries to meet the conflicting demands and constraints of cost, schedule, product reliability, safety, and performance. This paper deals with an application of the Weibull distribution which has found utility in the field of product reliability to the problem of establishing expiration dates for pharmaceutical and other health care products.

EXPIRATION DATING

Expiration or shelf-life limits are placed on pharmaceutical products to protect the user from low and sometimes high potency or concentrations of ingredients. The active ingredients may be degraded or become unavailable because of interactions with other ingredients or even the container itself. On the other hand, an ingredient may become more concentrated because of the evaporation or sublimation of other components.

Sometimes it is possible to include an excess of an ingredient at the time of manufacture to compensate for the aging process. However, cost and the safe limits of concentration are limiting factors. Substituents, or materials having equivalent biological performance but which tend to preserve the active ingredient, are sometimes used to obtain longer shelf life. For example, a glycerine having a lower water content than the U.S.P. glycerine might be used to reduce the degradation of an ingredient which oxidizes in the presence of water.

The mathematics of establishing shelf-life values based on experimental data have been given thorough exposure in the literature.^(1,2) A great deal of thought and investigation has been applied to problems of setting shelf life. Whole symposiums have been devoted to the general subject.⁽³⁾

TECHNOLOGY TRANSFER

Statistics is far from being a unified field. Practical statisticians tend to become heavily involved in the particular types of problems and the language of the field to which they apply their statistics. It becomes difficult to read technical literature written by other statisticians or workers in different fields of application because of language differences and different constraints on the application of even standard statistical methods.

For example, for those involved in the application of statistics to the control of quality in a machine shop, the word "tolerance" is used to connote a set of limits for a physical dimension such as the length of a shaft. Inspection data might give a distribution of shaft lengths for a sample of shafts taken from a production lot. The tolerance limits are fixed boundaries. On the other hand, in the application of statistics to biology, one might administer a dose of digitalis to a group of laboratory animals. The dosage would be increased until the animals' hearts stop beating. The amount or dose required to stop the heart is not the same for each animal. Thus there is a distribution of "tolerance" among the animals. Here the word tolerance is used to connote a distributed variable rather than a fixed boundary.

Communication problems reduce the opportunity to share ideas developed in one field of application of statistics with statisticians working in other fields.

THE EXPONENTIAL DECAY CURVE

The application of statistics to the field of reliability engineering has led to a number of interesting and powerful techniques. Of course, not all of these will find application in the pharmaceutical manufacturing field. The constraints on problems are different, and the ability to control various parameters is different. However, there appear to be some common types of problems and conditions which lead to the possibility of technology transfer.

One of the more common techniques used for setting shelf-life limits on pharmaceuticals and other health-care products employs the assumption that the concentration of an ingredient decreases exponentially with time. This kind of decay function (or model) is found to apply in many natural and man-made processes. For example, in the electronics field, an electrical charge stored on a capacitor leaks off through a shunt resistor giving an exponential decay to the voltage across the capacitor.

In general, this model can be used to describe any process in which there is a fixed rate of decay. That is, a fixed fraction of the substance which remains at any given time will be lost in the next time increment. The form of the exponential is shown in Figure 1.

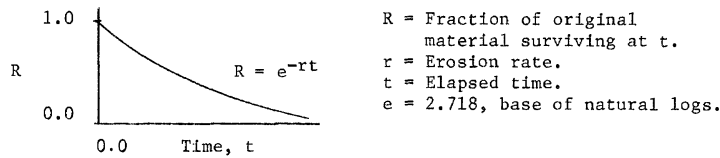


FIGURE 1. The exponential decay model.

This type of curve is common to both the pharmaceutical and the reliability fields. In the reliability field, it is often found that the erosion rate, r, which is called the failure rate, is not a function of time. If a fixed time interval of testing is used, the number of failures observed will tend to follow a Poisson distribution. See Figure 2.

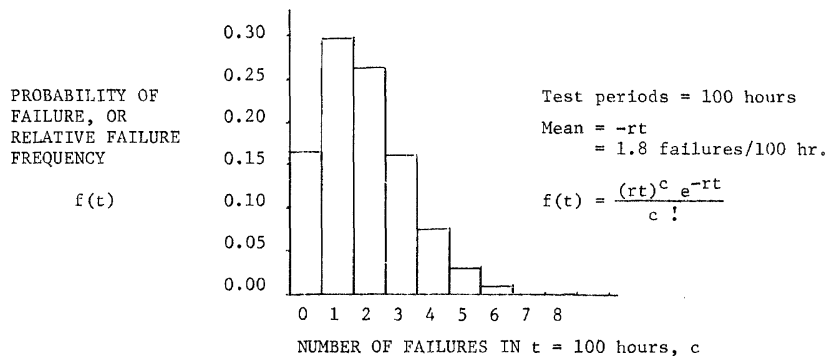


FIGURE 2. Poisson distribution of failures for fixed 100-hour test periods and a failure rate of 0.018 failures/hour.

A quick look at the equation for relative failure frequency in Figure 2 shows that it becomes the reliability equation of Figure 1 when the number of failures, c, is set equal to zero; that is, the probability of surviving t hours is the same as the probability of having zero failures.

$$f(t) = \frac{(rt)^c e^{-rt}}{c!} = \frac{(rt)^0 e^{-rt}}{0!} = e^{-rt} = R, \text{ for } c = 0$$

One application of the failure distribution type of model to pharmaceuticals was made by Berrittoni.⁽⁴⁾ He modeled the number of drug failures as a function of age.

Another way to examine pharmaceuticals arises out of the data which result from "stability testing." Samples of product lots are placed in storage under "typical" conditions. Periodically, samples are withdrawn from storage and assayed. The statistic typically reported is relative potency or relative concentration of some given ingredient. Thus there is no "failure data" as such. One is really tracking the shape of the decay curve of Figure 1.

UNSTABLE DECAY AND THE WEIBULL MODEL

Sometimes it is found that the decay curve seems to go through a change in life. That is, the erosion constant seems to be a function of time, or it may suddenly change its value after some period of time. From a diagnostic standpoint, it would be nice to know more about the nature of the change in the erosion constant. There is a type of erosion model which has a shape parameter which could give information on how the decay rate is changing. It is called the Weibull model.

In the early 1900's, Fisher and Tippet's investigation of the distribution of the largest and smallest observations in samples from a normal distribution led to the development of the extreme value distribution.⁽⁵⁾ Just before World War II, Waloddi Weibull rediscovered the extreme value distribution from a different approach. He applied the distribution model to problems involving fatigue and failure of materials. Shortly after the war, when the new breed of reliability engineers were searching for mathematical models for the equipment failures they were studying, Weibull's model seemed to fill the bill.⁽⁶⁾ It could handle the three life patterns that had been observed: burn-in (decreasing failure rate with time), useful life (constant failure rate), and wear-out (rising failure rate).

In essence, the Weibull model is a double exponential with three parameters: a shape parameter, a scale parameter, and a location parameter. The shape parameter (β), allows fitting to a decreasing ($\beta < 1$), constant ($\beta = 1$), or increasing ($\beta > 1$) erosion rate. The scale parameter (α) locates the 63% point on the cumulative distribution. The location parameter (γ) allows one to "start" life at any point in the age axis.

The equation for the Weibull model is:

$$R = e^{-\left(\frac{t - \gamma}{\alpha}\right)^\beta} \quad (1)$$

Where: α = Scale parameter.
 β = Shape parameter.
 γ = Location parameter, usually set to zero.
 t = Cumulative unit age.
 R = Fraction of original population surviving at t .

For many reliability applications, the location parameter is zero; and the Weibull model reduces to a two-parameter form.

The shape parameter (β) appears to have value in the analysis of data resulting from pharmaceutical stability or shelf-life studies. A value of β less than one indicates a decreasing erosion rate. This might be due to the exhaustion of a reagent that was causing erosion of the ingredient being studied. On the other hand, a $\beta = 1$ value would indicate the type of kinetics commonly assumed; i.e., a constant erosion rate.

The mechanics of erosion have been explored for some types of pharmaceuticals and give explanations for some of the observed data.^(7,8) For example, Hammett's linear free energy relation of sigma-rho, which allows one to estimate the effects on the stability of a compound when substituents are used, is in effect a shifting of the scale factor, (α), in the Weibull model.

$$\log (k/k_o) = \sigma \rho \quad (2)$$

Where: k = New erosion rate with substituent.

k_o = Original erosion rate.

σ = Substituent constant which depends solely on the substituent

ρ = Reaction constant, constant for all substituents.

Equation (2) may be rewritten:

$$\ln (k/k_o) = 2.303 \sigma \rho$$

$$k = k_o e^{2.303 \sigma \rho}$$

Let

$$\alpha = 1/k = 1/k_o e^{-2.303 \sigma \rho}$$

Substitution in equation (1) gives an equation of the Weibull form:

$$R = e^{-\frac{(t - \gamma)^\beta}{\alpha}} = e^{-tk} = e^{-t/\alpha}, \beta = 1, \gamma = 0$$

Thus, the Weibull gives two parameters, β and α , which separate out the two primary characteristics of erosion. This not only simplifies the statistical problems by reducing the number of parameters that must be estimated from the test data, but it reduces the amount of data required to detect problems in rate kinetics. By separating life "problems" into two characteristics which relate to the basic mechanics of decay, it is also much easier to obtain clues as to the physical cause of problems.

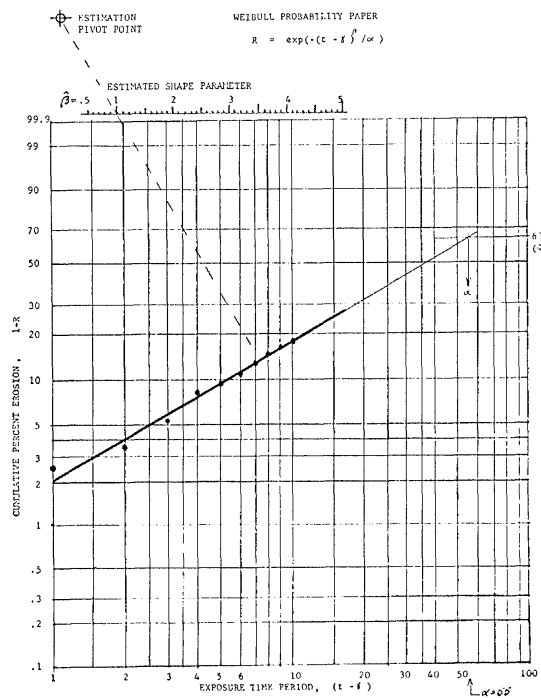
The two primary characteristics of erosion, β and α , answer the questions, Is the erosion rate independent of time, or does it increase or decrease with time? and Is there a difference in the basic erosion rate for two materials even if both have erosion rates that change with time?

WEIBULL PAPER

Graph papers have been developed to allow plotting the cumulative experience against time. By fitting a straight line to the data, an estimate of the size of the two parameters can be obtained. If a break or change of slope occurs, the location parameters for the two life patterns can be estimated; and the two curves, thus separated, give rise to different shape and scale parameters for the two life segments.

As with any attempt to estimate parameters from sampled data, one must be careful not to place undue confidence in them. Formal statistical techniques exist for placing confidence limits on various estimates. However, the value of graphic methods is that they give clues to the causes of the behavior observed with a minimum of calculation. Obviously, more formal methods are desirable when the consequences of being misled are serious.

An example of stability data plotted on Weibull paper is shown in Figure 3. The basic data are shown in Table I. These data were "contrived" or generated by simulation methods so that they do not represent any actual product. This was done not only to preserve proprietary actual stability data, but because by knowing for certain what factors generated the data, it is easier to illustrate how the Weibull parameters act as pointers to various conditions.



The data in Table I were generated by drawing random samples from a normal distribution which simulates assay and lot-to-lot variability in the concentration of the active ingredient. Natural logs of the assay results were taken, and the means of the log-concentration data are shown in the table. Ten time periods are shown. The time intervals are assumed to be equal. The erosion rate was assumed to be -0.02007 . This should theoretically cause a reduction to 90% of label claim at the end of ten time periods. The assumed concentration at release from the factory was 55 mg/ml with a 50 mg/ml label claim. The variability of assay and lot-to-lot differences was assumed to give a standard deviation of 2 mg/ml. The sample size used to generate each mean was 6.

TABLE I. SIMULATED STABILITY DATA												
TIME		0	1	2	3	4	5	6	7	8	9	10
THEORY	C	55.000	53.907	52.836	51.787	50.758	49.749	48.761	47.792	46.843	45.912	45.000
	R	1.000	0.9801	0.9607	0.9416	0.9229	0.9045	0.8866	0.8690	0.8517	0.8348	0.8182
	1-R	0.000	0.0199	0.0393	0.0584	0.0771	0.0955	0.1134	0.1310	0.1483	0.1652	0.1818
SAMPLED DATA	x1	53.96	56.05	52.78	53.89	48.24	51.41	47.87	48.05	47.01	41.90	48.08
	x2	56.59	52.51	54.68	55.25	51.63	49.69	49.61	47.97	48.78	49.02	46.13
	x3	57.09	53.30	56.03	49.24	55.64	50.62	47.59	47.52	46.48	48.32	43.50
	x4	56.73	50.99	50.71	54.51	50.16	45.22	47.09	47.60	44.87	46.10	46.02
	x5	54.78	57.40	52.56	51.69	48.13	52.31	50.77	47.53	44.87	46.08	43.34
	x6	53.42	54.94	52.99	49.73	50.24	50.10	51.35	47.07	47.69	46.84	45.29
\bar{u} = Avg $\ln(x)$		4.0148	3.9852	3.9753	3.9576	3.9242	3.9088	3.8922	3.8633	3.8418	3.8355	3.8147
$\bar{c} = \ln^{-1}(\bar{u})$		55.215*	53.793	53.265	52.333	50.621	49.839	49.019	47.622	46.609	46.617	45.363
$R = \bar{c} / c_0$			0.9743	0.9647	0.9478	0.9167	0.9027	0.8878	0.8625	0.8442	0.8389	0.8216
1-R			0.0257	0.0353	0.0522	0.0833	0.0973	0.1122	0.1375	0.1558	0.1611	0.1784

NOTES: * 55.215 represents the intercept ($t=0$) from the least squares line fitted to the averages of the $\ln(x)$ data points. This gives the "best estimate" of the initial concentration by utilizing the entire data set rather than using the $t=0$ sample.

The units for C, x1, and \bar{c} are mg/ml

The dashed line from the pivot point drawn at right angles to the fitted line passes through the shape parameter estimation scale at a value of $\beta=1$. This indicates that the data can be modeled by an exponential curve with a degradation factor which does not change with time. This is, of course, in agreement with the theoretical function which was used to generate the data.

The least squares line was fitted to the means of the natural logs of the concentration data. Any attempts to use the fitted line for purposes of forecasting or any of the standard regression analysis techniques rest on the assumption that the fitted numbers are normally (or nearly so) distributed. By using the mean of the natural logs, the law of the mean assures reasonable normality to the averages of six numbers even though the original numbers (natural logs of concentration in this case) are not normally distributed.

The general procedure for plotting Weibull paper has been described by J. N. Berrittoni,⁽⁴⁾ and an interesting method for testing the fit of data to the assumed model has been suggested by Weibull.⁽⁹⁾

A second example using simulated data is shown in Figure 4. In this instance, a decreasing erosion rate was programmed into the simulation for the first six time periods. This was used to simulate a drug with a reagent which gradually exhausts itself; and then after the sixth period, the erosion rate becomes uniform.

The Weibull parameters used in the simulation were:

A. Life period "A" (first six periods): $\beta = 0.6$, $\alpha = 8.22$, $\gamma = 0$

B. Life period "B" (after sixth period): $\beta = 1.0$, $\alpha = 16.82$, $\gamma = 0$

Examination of the plots in Figure 4 gives the following estimates:

A. Life period "A": $\hat{\beta} = 0.6$, $\hat{\alpha} = t_{\alpha}^{\beta} = 34^{0.6} = 8.3$, $\gamma = 0$

B. Life period "B": $\hat{\beta} = 1.0$, $\hat{\alpha} = t_{\alpha}^{\beta} = 16$, $k = \alpha^{-1} = .06$, $\gamma = 0$

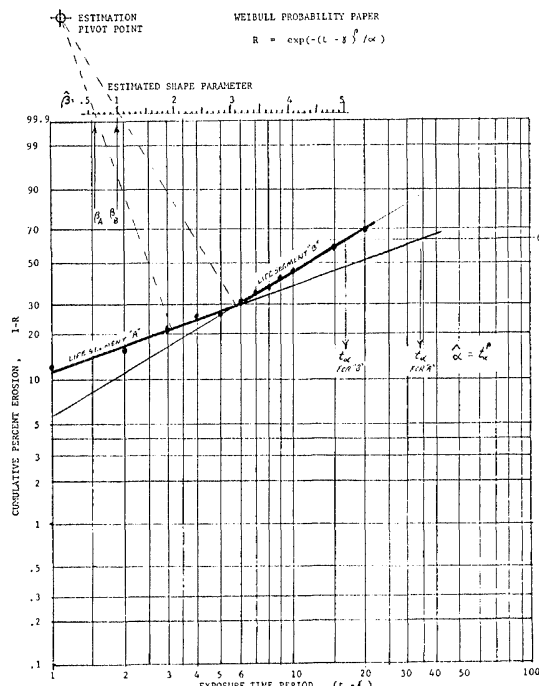


Figure 4. Simulated shelf life data with a change in erosion rate at the $t=6$ age.

CONCLUSIONS

The Weibull model provides a convenient means for separating the influences on degradation into three parameters. The shape parameter gives an indication of whether the erosion rate is increasing, constant, or decreasing with age. The scale parameter allows comparing two or more lots or types of material with respect to the basic rate of erosion independently of whether the rate is constant or not. The location parameter allows one to locate changes of life pattern and assign a point of origin to erosion.

Fitting data to Weibull paper is not an exact method of fit. However, it provides a rather quick and illuminating way of examining life patterns.

The Weibull model appears to have many diverse applications, and it merits consideration by investigators who are looking for a life model which has parameters that relate to the mechanical conditions which cause life patterns to exist.

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CAN CONCEPT-TO-CONSUMER SLIPPAGE BE PREVENTED?

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Many new products fail to make the transition from promising concept to successful marketed entity. The specific causes of failure can be any of a number of factors. However, top management may not be aware of how a strong quality assurance system might improve its success ratio.

The quality assurance role centers on technical slippage between concept and marketed product. The answers we hope to develop to the question of can this slippage be prevented will be particularly suitable for the developers of consumer products. If we were to include the space industry, for example, in the scope of this paper, I believe we would find that their top management was interested in, knowledgeable about, and involved in the support of a strong quality assurance system. This, because almost their entire effort is devoted to the effective application of existing technology. The technical issues, rather than marketing, sales, profit or budget, dominate management's time and energies. But in the retail consumer industries we have the other end of the applied technology spectrum. Here the technical issues tend to receive less of top management's time. Management tends to assume that an adequate organization is in place and that through it the marketing concept will become the desired product -- and will be available at the time and for the price prescribed by the marketing plan.

There is evidence, however, that reliance on the existing technical organization may not be enough. Even when the separate technical functions are strong, they may not be effective in channeling their strength toward the mutual objective. Even when the new product technical effort is strengthened by the clear assignment of centralized leadership, it is hampered by a limited time frame so that it is not possible, in the time available, to overcome long-standing obstacles to effective communication across functional lines.

Communication is viewed by some as just one chapter in the book of management. By others it is viewed as the whole book. This presentation leans heavily toward the second viewpoint. It says, in effect, that the management book on new product introduction is a book on effective communications -- primarily effective communication of the technical information necessary for the successful manufacture of the new product. The vital core of that communication network is a strong quality assurance system. Of course, there are also many organizational, financial, and decision-making pitfalls along the way; but top management appears to be aware of these and capable of dealing with them. This may not be so true of the technical pitfalls.

THE PRACTICAL REWARDS

The need then is to bring management "up to speed" on the role they can and must play to insure that their overall plan for a new product introduction includes a strong quality assurance system. Of course, this is a lot easier said than done; but, to avoid losing their interest while we get at the problem, we might hold their attention by suggesting that there are very practical rewards in store for a manager with this vision. The major rewards are more successes, earlier successes, and increased investment confidence in new products.

To spell out a bit how a sound quality assurance system can dangle such rewards before a manager:

1) More successes: While the goal is no slippage between promising concept and product in full-scale production, the realistic expectation is minimum slippage. Fewer failures, of either a temporary nature or a permanent one, can be expected when effort is organized to prevent any failures.

2) Earlier successes: This applies both to reaching satisfactory full-scale production earlier and to getting to payback point earlier. Time won't be wasted by the situation that occurs -- not uncommonly -- when a sound q.a. system is not in place and the product designed by Research is inadvertently redesigned by Engineering because of faulty communication and then redesigned by Manufacturing because their needs were not considered in the early phases. It has also been demonstrated that higher yields and greater productivity are the natural outgrowth of a sound q.a. system -- leading to meeting economic criteria sooner.

3) Increased investment confidence: This is really an outgrowth of the first two rewards. Some new products fail not because the concept could not eventually be made a reality, but because it took too long and required too much investment up front to bring this about. When the success ratio goes up and development time is reduced, top management has two hole cards that give it the confidence to put up the ante and stay in the game.

SOME PRINCIPLES OF A Q.A. SYSTEM

Because the quality assurance system is, in effect, the organized use of technical procedures and techniques, it is difficult to communicate to top management people. They are more interested in, and would better understand, the principles on which the q.a. system is based. Three of these should be mentioned:

First, quality is not an abstract idea but a collection of limiting factors (specifications) that set the yield/cost potential of a process.

Second, a quality assurance system is an interdepartmental communication system.

Third, the end product of the system is a process and product so well-defined that it can be readily maintained and further developed.

Let's develop each of these principles a little further.

Quality Is Not an Abstract Idea

The first step in the conversion from new product concept to continuous commercial production is the struggle to describe accurately in technical terms (specifications) all of those product properties which completely define it (i.e. define its quality). Management should not underestimate the difficulty of this first step or the difficulty communicating these specifications in a way that gives them permanence and immutability. No, quality is not an abstract idea. It is the concrete foundation.

An adequate quality assurance system can maintain the written specification to whatever extent it is developed by research and engineering. There need be no slippage on this first step.

Recognize, however, that each technical specification is a limit put on the manufacturing department. It will eventually, if not immediately, be an obstacle to manufacturing's ever-present objectives of lower cost operations, whether in productivity, yield or manning. The quality assurance system must be strong enough to protect the specification until such time as management chooses to change that specification.

Let's go on to the second principle.

Inter-departmental Communications System

The management of every manufacturing company has developed an organization which it believes can carry out the tasks at hand. Responsibilities are assigned; and we can assume each department clearly understands the limits of its responsibility and therefore -- at least in general terms -- the scope of its authority. However, unless the boundaries of these areas of authority are re-inforced or clarified within the framework of a quality assurance system, communications between departments becomes difficult and important technical issues frequently become jurisdictional issues. It is not uncommon under these conditions for the specifications to begin to shift. After all, marketing and manufacturing can't wait for the jurisdictional dispute to be resolved. So, slippage can occur by default. Management's commitment to the quality assurance system can give the necessary traction at this slippery point by establishing formal procedures for dealing with the "gray" areas.

And this leads us to the third principle that management should understand.

A Well-Defined Product

Our first principle, stressing the importance of specifications, looked at quality assurance's defensive contribution -- that is, how a strong q.a. system can keep specifications from being weakened or changed. But it would be desirable to have more from a quality assurance system than just barriers to slippage. The system should make a positive contribution -- initially to the most accurate conversion from concept to full-scale production; and then, beyond that, to the evolving product after it is in full-scale production.

A sound quality assurance system does make this positive contribution -- through the formal mechanism it establishes. This mechanism is the system characteristic most important to the development of the accurately defined product. It is the basis for establishing consistent, functional specifications for both product and process. Because a well-defined product can more clearly be understood by both the technical and the manufacturing communities, such a product should, in turn, lead to the least-cost process at design quality -- the one that gives management maximum flexibility and leverage in the market place.

ELEMENTS OF A Q.A. SYSTEM

Having said that management would not be "turned on" by the details of the quality assurance system, we must also say that it would certainly be "turned off" if we were not prepared to describe in some detail what the system is.

Let's spend a few minutes on what a viable quality assurance system looks like. In our experience there are half a dozen elements that must be combined in a formal, integrated way in such a system. We are not saying that this is a new view. It's an old one. In a way, we are trying to get into the mind of a craftsman to see how he works, to try to de-mystify what he does. If we could do this, we might see that the complex of people and equipment that make up today's manufacturing process is the embodiment of yesterday's craftsman. That's an oversimplification, of course, because size and sophistication add their own dimensions to the problem of quality control. But let's stay with the analogy because it does help us to make important points about the elements of the quality assurance system.

What the successful craftsman has or does comes to at least six basic elements. 1) He has access to all of the important facts about his skill. 2) He has acquired his skill through apprenticeship and training. 3) He follows an organized work plan or approach that has been shown to be reliable. 4) He periodically judges his performance against established standards of quality. 5) He makes sure his left hand knows what his right hand is doing. 6) When needed, he

takes his corrective action in a disciplined way based on the accumulated experience of his trade.

We can probably all agree that in general terms that sounds right. But we should get more explicit about what this means in a complex manufacturing unit.

Knowledge

The most important single element for manufacturing a product that meets the design criteria is the accumulation, in usable form, of the best available knowledge -- knowledge that issues from, and is binding on, all groups concerned. We've mentioned the importance of specifications and test methods, but that is only the beginning. All raw materials must be cleared; vendors must be reliable and must be monitored; facilities must be adequate; process equipment must be reliable and capable of producing design quality product.

Since many departments and technical groups can be involved here, all must feel they are contributors to the required body of knowledge and also must feel obliged to accept the contributions of others -- at least until differences can be resolved. All of these people are spokes of the wheel anchored to the documents that are at the hub. When management commits its support to the quality assurance system, it is committing support to whatever extra effort is required to develop and maintain the complete set of documents. Most technical groups find the chore of putting findings in writing rather anti-climatic and unrewarding compared to the joy of reaching those findings. Even more difficult for most is the struggle for consensus on those issues about which good men can technically hold differing points of view. Since the documents -- the records of accumulated knowledge -- are the basis for accurate, efficient communication and activity, their importance cannot be over-emphasized. The resources needed for their development and maintenance should be identified and funded up front. Then the leadership must be found to organize the people and establish the procedures that will overcome the obstacles.

Skill Development

All of the knowledge accumulated in the documents is of little use if it is not made available to the people -- operators, engineers, researchers -- who can use it. Particularly important is establishing adequate training programs for process operators. A successful training program is the one that gives the man with his hand on the throttle and valves all the guidance and information he needs to prevent the defect from occurring. Any compromise with the full training effort needed for this just increases the risk -- and probability -- of defects.

In most manufacturing processes, it is not art that is required of an operator, but skill. It is the training program that helps the individual make the transition from artist to skilled operator, someone who reliably turns out design quality.

From another point of view, the lack of sound training also limits the contribution the operator can make, as one of the spokes of the wheel, in feeding valuable information back to the document point at the hub. We have found that increased operator involvement generates useful ideas for improved process control. It also improves individual attitudes and helps standardize shift-to-shift operations.

A Plan

This element has to do with the thorough-going, organized approach to the production task at hand. Every step in the production sequence must be set down as it is in the mind of the craftsman, and then individuals must clearly be assigned their part in the integrated whole of the process. In other words, we have to overcome the problem we created by fractionating the craftsman's role into many parts. Nothing short of a detailed written plan with clear-cut assignments can make this happen.

At General Foods, we have found that this written plan approach makes it possible to identify and eliminate confusion about both individual and department responsibility. Early on, it was particularly helpful in clearly defining the operating department's responsibility for quality control.

The Quality Check

As part of the plan, each operator in the processing department should make as many quality measurements as required to keep his part of the process and product on target. But beyond that, we need the equivalent of the single pair of eyes of the craftsman who can see the total finished product and judge it independently and objectively. In a system, this independent view comes from the separate department (Quality Assurance) that maintains the skills for such overall product assessment.

Left Hand Tells the Right

Nothing underscores the difference between the individual craftsman and his many replacements in modern industry than the simple problem of the left hand (in one department) letting the right hand (in another department) know what is going on. So in industry we have to form the equivalent of the human network of messages that go from the craftsman's brain to his arm, leg, or finger with directions to take the correct action. The data must flow as freely and reliably as it does in the biological model. Data must arrive in the shortest time possible, because early clues help prevent drift and defects.

Experienced Handling

We said "help prevent" because the transmittal of timely, accurate data is, in most cases, not enough. Raw data is not as useful or powerful as analyzed data. So a final element deals with extracting from the data as much useful information as possible to make the process control decisions the correct ones. The more help an operator or his supervisor can get in the form of simplified data analysis techniques the better. Then the control actions can be specified and following them can be made a firm requirement. Where not specified, the decisions should be escalated to the next level of supervision. This is the equivalent of thinking about it a bit before taking actions which are risky because their effects are not proven.

Those are the elements of a sound quality assurance system. It depends at bedrock on the early and continuing input of research and engineering, but the effort for start-up and maintenance of the system falls to manufacturing. All three departments stand to benefit along with the company as a whole when a new product is close to the original concept. Manufacturing, in particular, stands to benefit longer-term through higher productivity, lower re-work of defects, and better communications with the technical community for process improvements.

WHAT CAN MANAGEMENT DO?

If we have held management's attention to this point with our promise of rewards, we might find them asking, "Exactly what is it you want us to do?" For starters we might suggest that they recognize that the quality assurance system is not the province of one department. Only with this recognition will come the multi-function accountability to go with the shared responsibilities. We should tell them to forget the stereotype of the Quality Assurance Department doing its own thing, i.e., keeping the boys honest (but possibly only after the value of the goods has inadvertently been eroded away). They should see the system as the thing. The Q.A. Department has a prime role in coordinating and monitoring system effectiveness, but the key to successful application lies elsewhere...

- In Marketing Research, for a clear and accurate measure of the importance of quality factors to the consumer.
- In Technical Research, for the accurate product design through a proven operational process which they put into the documents.

- In Engineering, for their efforts to convert Research development experience accurately through processing equipment which permits control of the essential variables.
- In Manufacturing, for the staffing, initial training and persistence in use of the system.

Each of these major participants in the system must be recognized (and rewarded) for his part in making the system work. Of course, the objective of getting the new product on stream is still primary; but we go so far as to say that achievement of that objective depends on the successful application of the system. Furthermore, without the system, accountability is frequently difficult to determine; and you end up without the ability to pinpoint weaknesses and then do something about them.

In addition, we should ask management to be anticipators. They should not wait for the new product to be looming on the horizon before they call the q.a. accountability roster. In other words, the quality assurance system should be in place in the existing organization before the new product gets much beyond the concept stage. Then the various functions are comfortable with their roles and responsibilities. They will have seen them work for existing processes and products. They can be held accountable.

CONCLUSION

The top management of companies which rely on new product entries for growth (or survival) should be aware of the importance of a strong quality assurance system, should know what such a system consists of, and should do their part to make such a system a reality.

- They can emphasize the need to develop and adopt a quality assurance policy and procedure that encompasses all of the departments that can affect quality -- so that the communications network is in place.
- They can insist that the system be in place and functioning before the new product leaves the development laboratory -- so that everyone is familiar with the system's workings.
- They can see that compensation/rewards are based on effective performance within and in support of the system.

The motivation to management action, of course, is the awareness of the possible rewards in new product conversions -- more successes, earlier successes.

USE OF REGRESSION ANALYSIS IN PACKAGING INSPECTION

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INTRODUCTION

In our operation, we receive annually between 75 and 100 million plastic containers for our many products. Each shipment is inspected by our Receiving Inspection Department for package conformity to specifications. A complete analysis can take from 45 to 90 minutes.

It was our feeling that the data generated by Inspection should be utilized in more ways than "go - no go".

A project was initiated to establish whether significant correlation exists between the weight and overflow capacities of plastic containers from a given mold. This information was evaluated for better utilization of inspection time, informing vendors of their performance, and improving line efficiencies through the reduction of product give away.

PROJECT

We annually use in excess of 75 million plastic containers for product packaging. These containers are received in shipments ranging in size from 20,000 to 250,000 pieces.

The sampling procedure employed is to select a minimum of ten cases of bottles from each shipment. In the selection process an effort is made to insure that each vendor manufacturing date and shift are represented. Each of the cases in the sample is opened and 20 bottles are inspected for manufacturing flaws. A representative from each cavity contained in the case is taken and the date and shift information is recorded on the bottle. These samples are taken to the laboratory for further analysis.

One of the measurements made is the determination of overflow capacity. Overflow capacity is important because it is through the proper establishment and enforcement of specifications that we control our solution usage. The label claim is the basis for establishing specifications for minimum overflow capacity. Allowances for head space and filling equipment variations are taken into consideration in arriving at the minimum overflow capacity. Target and maximum specification values are then obtained.

Each bottle brought to the laboratory for analysis is first weighed on an analytical balance. The weight data is recorded. The bottles are then filled with water (68 - 70°F) to the overflow of the bottle. The filled bottle is weighed and the empty weight is deducted to obtain the overflow capacity of the bottle.

General observation over the years had indicated an inverse relationship between bottle weight and overflow capacity. It was decided to examine this relationship and possibly exploit it as a time saving device in our inspection of plastic bottles.

ASSUMPTIONS AND METHODS UTILIZED

The plan was to examine the relationship of bottle gram weight and overflow capacity through the use of the Pearson Product-Moment Coefficient of Correlation. Several assumptions are implicit in our choice of methods.

- 1) Plastic bottles, in general, will increase in volume capacity as the weight of the bottle decreases, all other factors being held constant.

- 2) Bottles used in study were first visually inspected for physical defects. Defective containers were not used in the evaluation.

Two hundred ordered pairs of data (weight and overflow capacity) were randomly selected from one year's accumulated measurements. These ordered pairs were plotted on a correlation chart (Exhibit I). On each axis intervals were selected to yield a maximum dispersion of values over the chart. The frequency of measurements in each interval was then tallied. Calculations to obtain the values $\sum fx'$, $(\sum fx')^2$, $\sum fy'$ and $(\sum fy')^2$ were performed.

The value $\sum x'y'$ was calculated in a number of steps. First, the frequency of occurrence in a given square was multiplied by the value appearing in the upper right hand corner of that square. Second, positive and negative totals are obtained separately across the rows and entered in the appropriate column. The value $\sum x'y'$ is obtained.

Using the above values the following calculations are made:

$$\begin{aligned}
 1) \quad \frac{\sum fx'}{N} &= \frac{29}{200} = 0.145 & 2) \quad \frac{(\sum fx')^2}{(N)^2} &= (0.145)^2 = 0.021 \\
 3) \quad \frac{(\sum fx')^2}{N} &= \frac{787}{200} = 3.935 & 4) \quad \frac{\sum fy'}{N} &= \frac{402}{200} = 2.010 \\
 5) \quad \frac{(\sum fy')^2}{(N)^2} &= (2.010)^2 = 4.040 & 6) \quad \frac{(\sum fy')^2}{N} &= \frac{5452}{200} = 27.260 \\
 7) \quad \frac{\sum x'y'}{N} &= \frac{-1481}{200} = -7.405 \\
 8) \quad \sigma_x &= \sqrt{\frac{\sum (fx')^2}{N} - \frac{(\sum fx')^2}{(N)^2}} = \sqrt{3.935 - 0.021} = 1.978 \\
 9) \quad \sigma_y &= \sqrt{\frac{\sum (fy')^2}{N} - \frac{(\sum fy')^2}{(N)^2}} = \sqrt{27.260 - 4.040} = 4.819 \\
 10) \quad r &= \frac{\frac{\sum x'y'}{N} - \frac{(\sum fx')}{N} \frac{(\sum fy')}{N}}{\sigma_x \cdot \sigma_y} = \frac{-7.405 - (0.145)(2.010)}{(1.978)(4.819)} = -0.807
 \end{aligned}$$

The value of major importance is "r", (the Pearson Product-Moment Coefficient of Correlation). For our purposes a coefficient of correlation ≤ -0.70 was considered significant.

RESULTS

For all vendors whose bottles exhibited values of $r \leq -0.70$ calculations were continued in constructing a regression line and determining the standard error of the estimate.

Notation used for construction of regression line and standard error of the estimate determination are:

- 1) A_x - assumed mid-point of the distribution of x values, i.e., bottle weight where $x' = 0$.
- 2) A_y - assumed mid-point of the distribution of y values, i.e., bottle overflow capacity where $y' = 0$.
- 3) i_x - the interval size used for the x distribution on the correlation chart.
- 4) i_y - the interval size used for the y distribution on the correlation chart.
- 5) \bar{x} - the mean value of bottle weight calculated $\bar{x} = A_x + \frac{i_x (\sum fx')}{N} =$
- 6) \bar{y} - the mean value of bottle overflow capacity calculated $\bar{y} = A_y + \frac{i_y (\sum fy')}{N} =$

45.5	46.5	47.5	48.5	49.5	50.5	51.5	52.5	53.5	54.5	55.5	56.5	57.5	58.5	59.5	60.5	61.5	62.5	63.5	64.5	65.5
-100	-80	-60	-40	-20	0	20	40	60	80	100	120	140	160	180	200	220	240	260	280	300
-100	-80	-72	-64	-56	-48	-40	-32	-24	-16	-8	0	8	16	24	32	40	48	56	64	72
-80	-60	-52	-44	-36	-28	-20	-12	-4	4	12	20	28	36	44	52	60	68	76	84	92
-60	-40	-32	-24	-16	-8	0	8	16	24	32	40	48	56	64	72	80	88	96	104	112
-40	-20	-12	-4	4	12	20	28	36	44	52	60	68	76	84	92	100	108	116	124	132
-20	0	8	16	24	32	40	48	56	64	72	80	88	96	104	112	120	128	136	144	152
0	8	16	24	32	40	48	56	64	72	80	88	96	104	112	120	128	136	144	152	160
8	16	24	32	40	48	56	64	72	80	88	96	104	112	120	128	136	144	152	160	168
16	24	32	40	48	56	64	72	80	88	96	104	112	120	128	136	144	152	160	168	176
24	32	40	48	56	64	72	80	88	96	104	112	120	128	136	144	152	160	168	176	184
32	40	48	56	64	72	80	88	96	104	112	120	128	136	144	152	160	168	176	184	192
40	48	56	64	72	80	88	96	104	112	120	128	136	144	152	160	168	176	184	192	200
48	56	64	72	80	88	96	104	112	120	128	136	144	152	160	168	176	184	192	200	208
56	64	72	80	88	96	104	112	120	128	136	144	152	160	168	176	184	192	200	208	216
64	72	80	88	96	104	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224
72	80	88	96	104	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224	232
80	88	96	104	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224	232	240
88	96	104	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224	232	240	248
96	104	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224	232	240	248	256
104	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264
112	120	128	136	144	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272
120	128	136	144	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	280
128	136	144	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	280	288
136	144	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	280	288	296
144	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	280	288	296	304
152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	280	288	296	304	312
160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	280	288	296	304	312	320
168	176	184	192	200	208	216	224	232	240	248	256	264	272	280	288	296	304	312	320	328
176	184	192	200	208	216	224	232	240	248	256	264	272	280	288	296	304	312	320	328	336
184	192	200	208	216	224	232	240	248	256	264	272	280	288	296	304	312	320	328	336	344
192	200	208	216	224	232	240	248	256	264	272	280	288	296	304	312	320	328	336	344	352
200	208	216	224	232	240	248	256	264	272	280	288	296	304	312	320	328	336	344	352	360
208	216	224	232	240	248	256	264	272	280	288	296	304	312	320	328	336	344	352	360	368
216	224	232	240	248	256	264	272	280	288	296	304	312	320	328	336	344	352	360	368	376
224	232	240	248	256	264	272	280	288	296	304	312	320	328	336	344	352	360	368	376	384
232	240	248	256	264	272	280	288	296	304	312	320	328	336	344	352	360	368	376	384	392
240	248	256	264	272	280	288	296	304	312	320	328	336	344	352	360	368	376	384	392	400
248	256	264	272	280	288	296	304	312	320	328	336	344	352	360	368	376	384	392	400	408
256	264	272	280	288	296	304	312	320	328	336	344	352	360	368	376	384	392	400	408	416
264	272	280	288	296	304	312	320	328	336	344	352	360	368	376	384	392	400	408	416	424
272	280	288	296	304	312	320	328	336	344	352	360	368	376	384	392	400	408	416	424	432
280	288	296	304	312	320	328	336	344	352	360	368	376	384	392	400	408	416	424	432	440
288	296	304	312	320	328	336	344	352	360	368	376	384	392	400	408	416	424	432	440	448
296	304	312	320	328	336	344	352	360	368	376	384	392	400	408	416	424	432	440	448	456
304	312	320	328	336	344	352	360	368	376	384	392	400	408	416	424	432	440	448	456	464
312	320	328	336	344	352	360	368	376	384	392	400	408	416	424	432	440	448	456	464	472
320	328	336	344	352	360	368	376	384	392	400	408	416	424	432	440	448	456	464	472	480
328	336	344	352	360	368	376	384	392	400	408	416	424	432	440	448	456	464	472	480	488
336	344	352	360	368	376	384	392	400	408	416	424	432	440	448	456	464	472	480	488	496
344	352	360	368	376	384	392	400	408	416	424	432	440	448	456	464	472	480	488	496	504
352	360	368	376	384	392	400	408	416	424	432	440	448	456	464	472	480	488	496	504	512
360	368	376	384	392	400	408	416	424	432	440	448	456	464	472	480	488	496	504	512	520
368	376	384	392	400	408	416	424	432	440	448	456	464	472	480	488	496	504	512	520	528
376	384	392	400	408	416	424	432	440	448	456	464	472	480	488	496	504	512	520	528	536
384	392	400	408	416	424	432	440	448	456	464	472	480	488	496	504	512	520	528	536	544
392	400	408	416	424	432	440	448	456	464	472	480	488	496	504	512	520	528	536	544	552
400	408	416	424	432	440	448	456	464	472	480	488	496	504	512	520	528	536	544	552	560
408	416	424	432	440	448	456	464	472	480	488	496	504	512	520	528	536	544	552	560	568
416	424	432	440	448	456	464	472	480	488	496	504	512	520	528	536	544	552	560	568	576
424	432	440	448	456	464	472	480	488	496	504	512	520	528	536	544	552	560	568	576	584
432	440	448	456	464	472	480	488	496	504	512	520	528	536	544	552	560	568	576	584	592
440	448	456	464	472	480	488	496	504	512	520	528	536	544	552	560	568	576	584	592	600
448	456	464	472	480	488	496	504	512	520	528	536	544	552	560	568	576	584	592	600	608
456	464	472	480	488	496	504	512	520	528	536	544	552	560	568	576	584	592	600	608	616
464	472	480	488	496	504	512	520	528	536	544	552	560	568	576	584	592	600	608	616	624
472	480	488	496	504	512	520	528	536	544	552	560	568	576	584	592	600	608	616	624	632
480	488	496	504	512	520	528	536	544	552	560	568	576	584	592	600	608	616	624	632	640
488	496	504	512	520	528	536	544	552	560	568	576	584	592	600	608	616	624	632	640	648
496	504	512	520	528	536	544	552	560	568	576	584	592	600	608	616	624	632	640	648	656
504	512	520	528	536	544	552	560	568	576	584	592	600	608	616	624	632	640	648	656	664
512	520	528	536	544	552	560	568	576	584	592	600	608	616	624	632	640	648	656	664	672
520	528	536	544	552	560	568	576	584	592	600	608	616	624	632	640	648	656	664	672	680
528																				

Notation Used in Calculation of Pearson Product-Moment Coefficient of Correlation

- x - the independent variable; the gram weight of the bottle.
y - the dependent variable; the overflow capacity of the bottle.
N - the sample size.
f - the frequency.
x' - the deviation of x values from the assumed mid point of the x distribution.
y' - the deviation of y values from the assumed mid point of the y distribution.

- 7) r - Pearson Product-Moment Coefficient of Correlation.
- 8) σ_x - the standard deviation of x values (calculated by multiplying σ_x' by i_x).
- 9) σ_y - the standard deviation of y values (calculated by multiplying σ_y' by i_y).
- 10) Formula of Regression Line:
- $$y \text{ predicted} = \left(r \frac{\sigma_y}{\sigma_x} x \right) - \left(r \frac{\sigma_y}{\sigma_x} \bar{x} \right) + \bar{y}$$
- 11) Formula of Standard Error of the Estimate:
- $$S_{y,x} = \sigma_y \sqrt{1-r^2}$$

Calculations for Construction of Graph

$$r = -0.807$$

$$\bar{x} = A_x + \frac{i_x (\Sigma fx')}{N} = 55.5 + \frac{1(29)}{200} = 55.5 + 0.145 = 55.645$$

$$\bar{y} = A_y + \frac{i_y (\Sigma fy')}{N} = 854 + \frac{2(402)}{200} = 854 + 4.02 = 858.02$$

$$\sigma_x = i_x \sigma_x' = (1)(1.978) = 1.978$$

$$\sigma_y = i_y \sigma_y' = (2)(4.819) = 9.638$$

$$\begin{aligned} y \text{ predicted} &= \left(r \frac{\sigma_y}{\sigma_x} x \right) - \left(r \frac{\sigma_y}{\sigma_x} \bar{x} \right) + \bar{y} \\ &= \left(-0.807 \frac{9.638}{1.978} x \right) - \left(-0.807 \frac{9.638}{1.978} 55.645 \right) + 858.02 \\ &= -3.932x - 218.807 + 858.020 \\ &= -3.932x - 1076.827 \end{aligned}$$

<u>x</u>	<u>y predicted</u>	$S_{y,x} = \sigma_y \sqrt{1-r^2}$
53	868.431	$= 9.638 \sqrt{1.0 - 0.651}$
55	860.567	$= 9.638 (0.591)$
57	852.703	$= 5.694$
60	840.907	

$$95\% \text{ confidence limit} = (S_{y,x})(2) = 11.388$$

A graph of the regression line (Exhibit II) was constructed using the above calculations with bottle weight as the independent (x) variable and overflow capacity as the dependent (y) variable. The specified limits for these values (gram weight and overflow capacity), are used to construct a "target" area on the graph.

The regression line is plotted through this target area. An area of twice the standard error of the estimate ($2 S_{y,x}$) is constructed above and below the regression line. The band described, represents the 95% confidence limits for overflow capacity at a given bottle weight.

Weight control limits were established once the regression line has been plotted with 95% confidence limits. The lower weight control limit is established at the point of intersection of the lower 95% confidence limit ($y \text{ predicted} = -3.932x + 1076.827 - 11.388$) and the minimum specified overflow capacity ($y = 841 \text{ cc's}$). Bottles which have a gram weight of 57.08 grams will have overflow capacities higher than the specified minimum, 95% of the time.

The upper control limit is established at the point of intersection of the regression line and the maximum specified overflow capacity. Bottles which have a gram weight of 53.4 grams will have an overflow capacity within the specified limits,

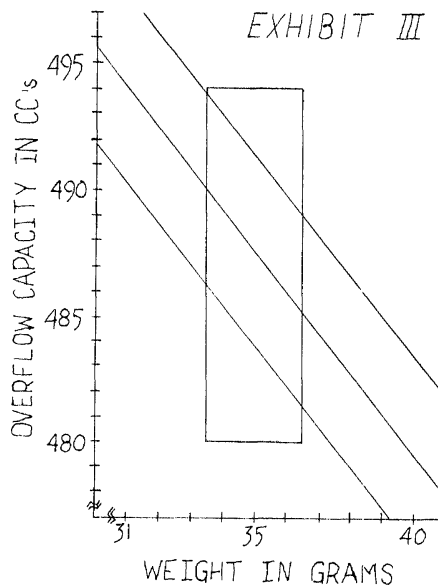
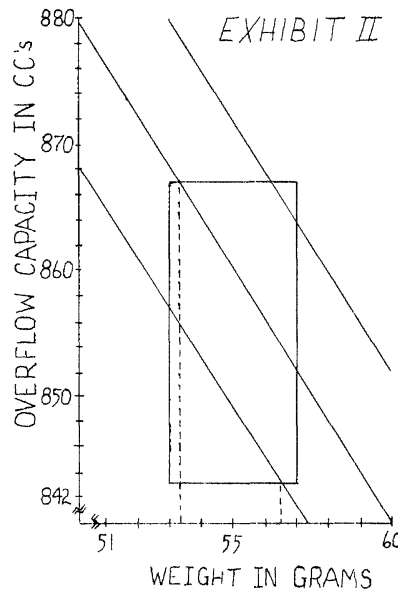
50% of the time. All bottles having weights within the control limits need not be measured for overflow capacity. We can be assured that bottles within these control limits will meet our minimum specified overflow capacity more than 95% of the time and will not exceed our maximum specified overflow capacity more than 50% of the time. Using the values for the average and standard deviation of weight, it can be seen that nearly 70% of the bottles received will not require verification of overflow capacity.

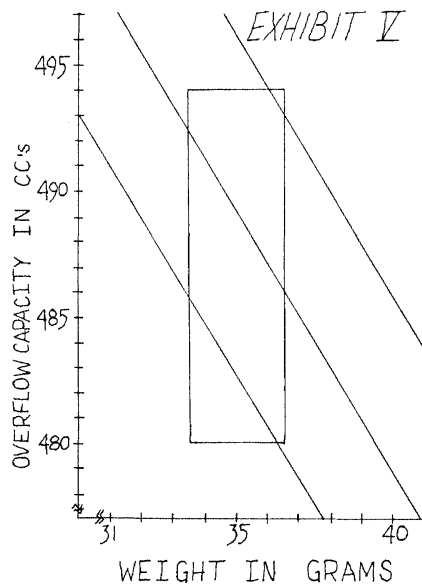
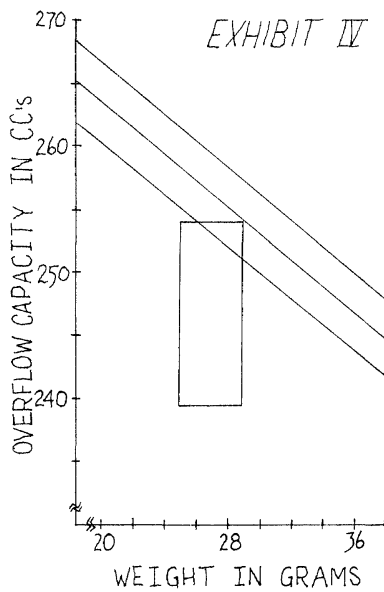
The maintenance of the plan calls for the weighing of 20 bottles from every shipment received. Those bottles with weights outside the control limits must be filled and checked. It was also decided that audits should be made to verify the system.

The graph can also yield other information. For a given weight, the standard error of the estimate can be an indication of how much control the molder has over the various variables affecting bottle weight. These variables would include distribution, wall thickness, cycle time, heat, etc. All of these variables affect the values of overflow capacity slightly. If they are under perfect control their effect on the overflow capacity should be non-existent. The standard error of the estimate can serve as an index of the precision of the molding process.

The graphs which are constructed of the regression lines can also serve other useful purposes. Though the information is available from other sources, the graph serves as an impressive visual aid. Three graphs are used to illustrate this point. Exhibit III portrayed excellent control over the molding process. The control exhibited over both weight and overflow capacity is both accurate and precise. Exhibit IV indicates that the vendor is precise but not accurate. In this particular instance, repairs were requested on the molds to bring the capacity back into specification. Exhibit V illustrates accuracy in meeting the specification, but the precision is not as good as the vendor represented by Exhibit III.

This information can be used both internally in vendor evaluation, and in discussing with a vendor on improvements.





CONCLUSION

This method has proved a reliable time saving device in the inspection of plastic bottles. The analysis was performed on all of the vendors of bulk plastic containers. By utilizing this method, we recognized substantial time savings in Receiving Inspection.

The use of this analysis has also been helpful in suggesting corrective action to our suppliers.

The process has prevented adverse effects in our manufacturing operation. When used in conjunction with a policy of strict enforcement of specified limits, product give away is held to a minimum.

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INTRODUCTION

Statistics can be viewed as the mathematical science that allows inferences to be made regarding unknown and underlying structures from observed numerical data. For example, based on the data from 500 patients in a clinical drug trial, inferences are drawn as to the effect of that drug upon a general population. Various specialties within the general area of statistics have developed to meet particular sets of needs. Nonparametric statistics, for instance, permits inference with less rigorous assumptions on the data structure, while sequential analysis is most applicable when the data arises sequentially. Multivariate statistical analysis permits the analysis of data where multiple observations are taken on each experimental unit, e.g., observations describing a given patient's clinical response over time. It should be stressed that these various specialties within statistics in no way partition the science of statistics. There is in fact much overlap and boundaries are very blurred - nonparametric multivariate statistical analysis is an active area of application and research. Many of these areas of statistics, such as multivariate analysis have their roots in 19th century mathematics; but it is only recently with the popularization of high speed computers, that the widespread application of these methodologies is possible.

It is the purpose of this overview paper to discuss the conceptual basis of multivariate statistical analysis with emphasis on examples arising from pharmaceutical research. Before presenting the actual methodological discussion, we consider some examples where a natural approach to viewing the data is a multivariate one.

Chronic Toxicity Studies

In order to assess the potential toxicological effect of a given compound, long term studies over months or years are done, usually with rats or dogs. Such an experiment might yield, for example, weekly body weights over 52 weeks from 400 rats, 100 each receiving either control, low dose, middle dose or high dose. In this case, there are $4 \times 100 \times 52 = 20,800$ observations. Oftentimes data such as this is analyzed for each of the 52 weeks separately. However, it seems more appropriate to view the 52 data points for each rat as an entity in itself, i.e., view the collection of these 52 variates in a multivariate fashion. In multivariate analysis one employs these collective entities, thereby making use of all the rat's data including the weekly interrelationships and body weight growth patterns over time.

Diagnosis

For certain syndromes multiple item questionnaires are employed for diagnosis and for quantification of the severity of the syndrome (e.g., diagnosing and measuring anxiety, hyperkinesis, or alcohol withdrawal). For example, if one has a 20 item questionnaire, it is natural to view an individual's response to this questionnaire as a collection of 20 data points, rather than deal with each data point or questionnaire item separately. One can then study the interrelationships among responses; or identify subgroupings or combinations of questionnaire items that are more meaningful or useful in diagnosing certain subtypes of the syndrome.

Drug Evaluation

In order to compare several drugs for efficacy and safety, there are usually multiple variables for measuring efficacy and safety. Standardly, for evaluating safety, clinical laboratory tests are employed. It is possible to examine each laboratory parameter separately in order to assess relative drug safety, but often it is more desirable and meaningful to view the laboratory results collectively (multivariately) or, at least, certain subsets (e.g., those parameters pertaining to the liver) collectively.

MULTIVARIATE METHODS: BASIC CONCEPTS

The sample mean and variance, as well as the Gaussian distribution, are familiar concepts of univariate statistics, where one deals with a single variable at a time. The sample mean measures the center of a sample while the sample variance measures the dispersion of a sample. The bell-shaped Gaussian or normal distribution is quite often assumed to represent the underlying distribution of the data. Many of the usual univariate methods, e.g., t-test, F-test, are based on the Gaussian assumption.

Natural analogues of these concepts exist in the multivariate case. Suppose that X_1, \dots, X_q represent the q data points associated with an experimental unit. For example, q may be 52 and X_1, \dots, X_{52} represent a given rat's 52 weekly body weights. It is convenient to represent these q data points as a vertical array and then use the simplified notation \tilde{X} to represent the collection of these q data points, where we write

$$\tilde{X} = \begin{bmatrix} X_1 \\ X_2 \\ \vdots \\ X_q \end{bmatrix}.$$

The entity \tilde{X} is usually called a data vector of dimension q . If there is a sample of size n of such sets, this sample is denoted $\tilde{X}_1, \dots, \tilde{X}_n$. For instance, if a 20 item questionnaire ($q = 20$) is administered to a sample of 35 individuals ($n = 35$), the data vector is

$$\tilde{X} = \begin{bmatrix} X_1 \\ \vdots \\ X_{20} \end{bmatrix},$$

and the sample is denoted by the 35 data vectors $\tilde{X}_1, \dots, \tilde{X}_{35}$.

For a given sample of multivariate entities of dimension q , X_1, \dots, X_n a multivariate sample mean $\bar{\tilde{X}}$ measuring the center of the data is defined by

$$\bar{\tilde{X}} = (\tilde{X}_1 + \dots + \tilde{X}_n)/n,$$

where these vertical vector arrays are combined by adding corresponding entries and then dividing by n . The multivariate analogue of variance is slightly more involved and is given by numbers arranged in square array fashion. This square array is called the sample variance - covariance matrix, denoted by \tilde{S} , and defined by

$$\tilde{S} = \begin{bmatrix} s_{11} & s_{12} & \dots & s_{1q} \\ s_{21} & s_{22} & \dots & s_{2q} \\ \vdots & \vdots & \ddots & \vdots \\ s_{q1} & \dots & \dots & s_{qq} \end{bmatrix},$$

where s_{ij} is the sample variance (unbiased) of the i th entry of \tilde{X} and s_{ij} is the sample covariance between the i th and j th entries of \tilde{X} . The sample correlation between the i th and j th entries of \tilde{X} is $s_{ij}/(s_{ii}^{1/2} s_{jj}^{1/2})$.

Analogous to the univariate case, there is a multidimensional Gaussian or normal distribution. Many of the standard multivariate techniques we consider are based on the assumption that the underlying distribution for the observed multivariate data is multivariate Gaussian. It is well known that the univariate Gaussian distribution is bell shaped; however, the shape of the multivariate Gaussian normal is more complex and impossible to depict graphically for dimensions greater than three. The bivariate normal distribution can be described as having an elliptically mounded shape, and suitable cross-sections are, in fact, bell-shaped.

Example 1. (Based on Tatsuoaka (p. 82, 1971).) Suppose in testing anti-anxiety agents, A and B, two hypothetical rating scales are employed: perceived stress and anxiety (where for both scales higher scores indicate higher perceived stress or anxiety). Ten patients are randomly divided into two equal groups, one group to receive A and the other B. At the end of six weeks of treatment, perceived stress scores and anxiety scores are obtained for each of the ten patients, with the data pairs as follows:

	Drug Group A					Drug Group B				
Perceived Stress	[3]	[9]	[16]	[19]	[24]	[7]	[12]	[18]	[24]	[28]
Anxiety	[6]	[6]	[8]	[13]	[12]	[11]	[14]	[18]	[18]	[20]

In this case, we have two samples of size 5 of bivariate ($q = 2$) observations. The multivariate means \bar{X}_A for Group A and \bar{X}_B for Group B are

$$\bar{X}_A = \begin{bmatrix} 14.2 \\ 9 \end{bmatrix}, \quad \bar{X}_B = \begin{bmatrix} 17.8 \\ 16.2 \end{bmatrix}$$

and respective sample variance-covariance matrixes S_A and S_B are

$$S_A = \begin{bmatrix} 68.7 & 24.0 \\ 24.0 & 11.0 \end{bmatrix}, \quad S_B = \begin{bmatrix} 73.2 & 29.8 \\ 29.8 & 13.2 \end{bmatrix}.$$

Note that the sample correlations between perceived stress and anxiety for drug Group A and B are .87 and .96, respectively.

MULTIVARIATE METHODS: UNIVARIATE EXTENSIONS

One type of application of statistics often encountered is making inferences concerning the means of the variables of interest. The usual univariate methods dealing with this situation include among others Student's t , analysis of variance, analysis of covariance and regression. Corresponding to each of these univariate procedures is a multivariate extension.

Student's t is most usually employed to test whether the means of two groups (or populations) are the same. For example, if one were comparing the effects of two drugs on a given set of laboratory parameter, an independent samples Student's t may be employed. The multivariate procedure corresponding to Student's t is Hotelling's T^2 . Suppose X_1, \dots, X_n is a sample of size n from a q -variate multivariate Gaussian distribution and Y_1, \dots, Y_m is a sample size m from a q -variate multivariate Gaussian distribution. Hotelling's T^2 can be used to test whether or not the q -variate population mean of the first sample is equal to the q -variate population mean of the second sample. The crucial consideration here is that the q means are collectively tested, one population against each other. Hotelling's T^2 yields a single statistic which allows the simultaneous comparison of the q means from the first population with the corresponding q means from the second population. Consider studying, for example, the possible effects of two drugs on the change in the three liver laboratory parameters SGOT, SGPT and LDH. It would be appropriate to use a Hotelling's T^2 to compare the values from one drug group with the other. This would jointly test possible drug effect on these three parameters taking into account the correlations among them.

Example 2. For the data given in Example 1, we wish to test whether or not individuals receiving drugs A and B have the same mean perceived stress scores and anxiety scores after six weeks of treatment. First note that if univariate Student's t test were conducted for each score separately, the resultant levels of significance for differences between drugs are $p \leq .55$ for perceived stress, and $p \leq .012$ for anxiety. The level of significance from Hotelling's T^2 which jointly tests perceived stress and anxiety is $p \leq .002$. Note that the multivariate level of significance in this example is smaller than either univariate level for this pair of highly correlated variables.

Univariate analysis of variance is used to test for differences among the structures of numerous population means. The corresponding multivariate procedure is termed, appropriately, multivariate analysis of variance. While the mathematics of deriving multivariate analysis of variance tests are involved, the interpretation of the test statistics can be made reasonably readily by analogy with the corresponding

univariate test statistics. For the chronic toxicity example in the Introduction, the multivariate version of one-way analysis of variance could be employed to test collectively whether or not there is any difference among the four treatments for the entire set of 52 weekly body weights. The one-way multivariate analysis of variance in this case would yield a single level of significance comparing all four treatments based on the year's weekly body weight data. (More typically in treating data of this type the weekly data would be averaged to obtain monthly body weight data and then comparisons made based on the monthly data.) If, in this example, there were two months' weekly body weight data for each rat prior to treatment, one could employ multivariate analysis of covariance to test for treatment differences after adjusting for each rat's pre-treatment body weight data. The interpretation of these results would be similar to univariate analysis of covariance.

Univariate regression theory allows the study of the effect of several independent variables on one dependent variable. In an industrial chemical process, one could use regression analysis to study the effect of temperature, pressure and purity of raw materials upon yield. In multivariate regression theory, more than one dependent variable is allowed. For example, multivariate regression theory would permit the assessment of the effect of temperature, pressure and purity of raw materials upon yield and finished product purity, jointly. Any correlation between yield and finished product purity would be taken into account by the analysis. A multivariate regression equation for this chemical example would be of the following form:

$$\begin{bmatrix} \text{Yield} \\ \text{Post-Purity} \end{bmatrix} = \begin{bmatrix} a_1 \\ b_1 \end{bmatrix} \times \text{Pressure} + \begin{bmatrix} a_2 \\ b_2 \end{bmatrix} \times \text{Temp} + \begin{bmatrix} a_3 \\ b_3 \end{bmatrix} \times \text{Pre-purity} .$$

MULTIVARIATE METHODS: STUDYING RELATIONSHIPS

One of the essential reasons for a multivariate approach to statistical analysis is to be able to study and understand the relationships within a collection of variables. By the essence of multivariate analysis, there is no analogue of this concept within univariate statistics. Depending on the type of relationship being considered, one usually defines a suitable numerical measure that quantifies the strength of the relationship. The commonly employed measures are intuitive, and many of their mathematical and statistical properties are known and tabulated. A broad class of these methods, often called correlational methods, are intimately tied to the multivariate Gaussian assumption, while other classes of methods are much less dependent on the data having a Gaussian distribution. It is the former class of methods that are discussed in this section and a brief discussion of the latter is given later.

In the case of two variables, the strength of the relationship between them depends on how well one variable predicts the other. The strongest possible relationship occurs when knowledge of one variable perfectly predicts the other and the weakest possible relationship is when knowledge of one variable provides no information concerning the other. For example, if one variable represents an object's length in inches and the other variable in centimeters, then these two variables are perfectly related (in fact, perfectly linearly related). On the other hand, it is clear that the annual California wine production is totally unrelated to the number of home runs hit in the World Series.

The correlation coefficient, with a numerical range of -1 to +1, is the most commonly used measure of relationship when dealing with two variables. If its value is 1 (or -1), then there is a perfect positive (or negative) relationship. Moreover, this perfect relationship is a linear relationship. A value of zero indicates a complete lack of relationship. Intermediate values describe degrees of relationship so that a correlation of .83 indicates a stronger relationship between two variables than a correlation of .27. In Example 1, the sample correlations of .87 and .96 both indicate a high degree of relationship between perceived stress and anxiety, with drug Group B showing an apparently slightly stronger relationship. It is noted that a positive correlation coefficient indicates that essentially both variables are increasing or decreasing together, while a negative correlation indicates that if one variable is increasing then the other is decreasing. When comparing the strength of relationship between a positive and negative correlation, the absolute values should be used, i.e., ignore the minus sign on the negative correlation.

While correlation allows the measurement of relationship between two variables, it sometimes is desired to measure the relationship between two sets of variables. For example, in a 20 item questionnaire, the first 8 items may be associated with a Factor 1 and the remaining 12 items associated with a Factor 2. In studying the relationship between Factor 1 and Factor 2, one is examining, in essence, the relationship between the first 8 variables and the remaining 12 variables. The canonical correlation coefficient measures this type of relationship. Its properties are similar to those of the correlation coefficient, ranging from -1 to 1 and with a value of zero indicating no relationship. A value of .64 implies in this example that there is some weighted sum of the first 8 items that has a correlation of .64 with some weighted sum of the other 12 items, and that the highest possible correlation achievable in such a weighted sum fashion is .64. The actual weights that comprise the sum may be interpretable and the weighted sum variables are called the canonical variables. In the special case where the first set of variables has only one member, the canonical correlation coefficient is called the multiple correlation coefficient.

On occasion, one measures relationships between variables or set of variables when there is knowledge or conditions about an additionally related variable. Suppose that in addition to the questionnaire values for an individual, I.Q. is also available. One may wish to study the relationship between two questionnaire items under the condition that the individual have an I.Q. of 140. The partial correlation coefficient measures such conditional relationships. Much less commonly employed, but still useful is the conditional canonical correlation coefficient.

MULTIVARIATE METHODS: STRUCTURE

In this section, we consider some methods for understanding the underlying structure of the multivariate data. In a univariate situation, the data variable itself fully and completely describes the underlying data. For multivariate data, it's possible that the full set of variables are required to describe the basic underlying structure of the data. However, it's often possible to find a simpler set of variables than the full set that fully depicts the basic structure of the data. This simpler set of variables may be a sub-collection of the original set or may be certain combinations of the original variables. For this reason, the methods we consider are often called dimensionality reduction methods, i.e., they permit the studying of a set of q variables by examining a smaller set of variables. For the chronic toxicity example, the 52 weeks of data is a large set of variables with which to deal. It would be highly desirable to be able to find a much smaller set of variables that contains essentially the same information as the original variables.

Structural multivariate methods can be viewed as falling into two general classes depending on whether or not comparisons across groups are important. In the non-comparative case where one is interested in understanding the structure of a given set of data, there are the two wellknown techniques of principal components and factor analysis. Both methods seek to represent the structure or variability in a q dimensional set of variables in terms of a smaller number of variables each variable having zero correlation with another. Principal components achieves this by considering combinations of the original variables while factor analysis postulates as the reduced set of variables unknown factors which require interpretation.

From a purely statistical point of view, factor analysis more formally takes into account the desired reduction in dimensionality but requires more interpretation, while principal components less formally handles the dimensionality reduction, but does not require as much interpretation.

For a given set of data, both principal components and factor analysis depend only on the sample variance - covariance matrix from that data. While both methods should be employed for large sets of variables, e.g., 20 item questionnaire or 52 weeks of body weight data, we consider a simple example illustrating principal component analysis.

Example 3. For the data in Example 1, we wish to find for Group A the principal components corresponding to the perceived stress scores and anxiety score. The first principal component is the variable equal to $.94 \times \text{stress} + .34 \times \text{anxiety}$ and the second principal component is the variable equal to $.94 \times \text{anxiety} - .34 \times \text{stress}$. The variance of the first principal component is 77.38 and of the second is 2.32, with the principal components being uncorrelated. A

standard interpretation of these results would be as follows. Because 77.38 is so much larger than 2.32, the full information for both variables stress and anxiety is "essentially carried" in the first principal component. This first principal component places more emphasis on perceived stress than anxiety, but is difficult to interpret further.

When dealing with underlying structure when comparisons between groups are important, the techniques of discriminant analysis and canonical variables are appropriate. Canonical variable analysis is a dimensionality reduction technique while discriminant analysis is technically not such a technique. However, we include discriminant analysis in this section because of its close affinity to the other methods discussed.

In the case of 2 groups (as discussed in an earlier section), canonical correlation and canonical variables are a measure and variables, respectively, that relate the structure of one group with that of the other in such a way as to maximize certain correlations. As in principal components, there are multiple canonical variables (each uncorrelated with each other) for each group. The canonical variables for each group are weighted sums of the original variables for that group, with the correlation between the first canonical variables, i.e., the canonical correlation, being as large as possible. In essence, these two first canonical variables indicate the underlying variable in one group that is most related to an underlying variable in the other group.

Suppose based on previously obtained data, sample multivariate means and variance - covariance matrices were available for each of several groups. Discriminant analysis allows the classification of a new data point into one of these several existing groups. For example, suppose based on a thorough medical examination, a group of school-age children was broken into four groups: normal, mildly hyperkinetic, moderately hyperkinetic, and severely hyperkinetic. A 20 item hyperkinesis questionnaire was administered to each group with means and variance - covariance matrices being computed. Now based on the questionnaire data from a new child, one desires to classify that child into the group which the child belongs. Discriminant or classification methods classify the child in such a way as to minimize a misclassification. Typically, one inputs to a discriminant procedure prior feelings about the relative sizes of the groups and also rough costs associated with a misclassification, e.g., classifying a normal child as hyperkinetic or vice versa.

Cluster analysis and path analysis are two other structural methods worth mentioning. Cluster analysis is a set of techniques that allows one to take a multivariate data set and sub-divide the data into relatively homogenous groups. There are numerous clustering techniques with substantive differences among them. Path analysis studies the relationships among observed variables and hypothesized underlying variables where the general form of the relationships (path diagram) must be specified in advance.

MULTIVARIATE METHODS: MISCELLANEA

Most of the commonly used methods previously discussed substantially rely on the fact that the data has an underlying Gaussian distribution. There is a virtual cornucopia of methods that assume other underlying distributions or just general forms of underlying distributions. It would be impossible to discuss more than a few such techniques here.

In categorical data, an entry in the multivariate array would only indicate into what category that entry falls. Suppose one has a three dimensional data array where the first entry is 0 or 1 if the patient improved or not, the second entry is 1, 2 or 3 according to whether the patient received drug A, B or C, and the third entry is 1, 2, 3 or 4 according to the staging of initial severity of that patient's disease. Log-linear categorical analysis permits one to study the individual or combined interrelationships of such data, relating, for example, improvement to treatment to disease severity.

In dealing with measures of relationship for non-Gaussian data, there are innumerable "measures of association," or types of association each with different properties, pros and cons. For illustrative purposes, we list a few: rank correlation coefficient (useful for nonparametric or rank data), total positivity of order 2 (useful in reliability theory) and maximal correlation (a non-Gaussian analogue of canonical correlation).

For handling multivariate data in a "life-testing" context, there is multivariate reliability theory. There are, for example, several multivariate extensions of the important univariate exponential distribution. These multivariate exponential distributions permit modeling of complex systems where individual components have correlated times to failure, but components viewed by themselves have an exponential failure time.

COMMENTS

It should be stressed again that the methods given have been presented at an intuitive level. Heuristic arguments and "illustration by example" have been liberally employed. Very little emphasis was placed on formality and particularly on the necessary assumptions for each method. Obviously one should be aware of some of the more formal details in using any of these procedures.

There are many very good texts for further reading in multivariate analysis ranging from elementary to highly mathematical. Included among the former category are - Harris [1975], Tatsuoaka [1971] and Van de Geer [1971], and included among the latter are Anderson [1958], Dempster [1969], Press [1972] and Roy [1957]. Other references that combine both theory and application include Bishop, Fienberg and Holland [1975], Bock [1975], Gnanadesikan [1977], and Morrison [1967]. Each of these noted references would provide directions for further readings.

There are at least three multi-purpose statistical program packages that include the basic multivariate statistical programs. They are BMDP - 1977, SAS - 1976 and SPSS - 1975. Clyde's [1969] MANOVA is purely a multivariate program. For references to other multivariate statistical programs, see the references, especially Press and Gnanadesikan.

By its very nature, multivariate statistical analysis has a richness not found in univariate statistics. It has been our attempt in this overview paper to convey this richness by presenting some of the common, but highly useful multivariate techniques.

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QUALITY ASSURANCE IN ENVIRONMENTAL REGULATIONS

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INTRODUCTION

A common complaint by practicing statisticians is that engineers and scientists feel perfectly capable of "doing statistics" while at the same time believing a statistician is totally incapable of understanding the technical aspects of their problems. In discussing the role of the statistician in environmental law, I am fully aware that what I say may be viewed as the irrelevant ramblings of a scientist-meddler by many who formulate and interpret environmental policy. Yet, I am also aware that these same persons take as part of their license the interpretation of complex technical evidence, often without the benefit of full and complete consultation with unbiased experts. This situation has always been mystifying to me, as is the question of why environmental regulations do not, in general, reflect in their language even basic statistical principles. The answer is complex, revolving around a communications problem between those engaged in lawmaking and law enforcement and those who provide the scientific basis for policy formulation.

The space allotted allows only a cursory glance at the complex area of environmental regulation. If this paper generates sufficient interest to spur some to investigate further and take some action, then its objective is accomplished.

DISCUSSION

The regulatory process in general, and the environmental regulatory process in particular, is necessarily a judgmental process. Scientific evidence can be and has been used to help demonstrate a need for regulation. It can be and has been used to help define what is to be regulated and the extent of the regulation in terms of standards or criteria for performance. However, we all realize that scientific data are not perfectly definitive in general and are subject to interpretation. The statement that compound XYZ is a carcinogen begs the questions, to what population, what are the risks to this population, and how do these risks stack up against potential benefits? If it is decided to regulate compound XYZ, what criteria should be used for the regulation? What levels of XYZ can be tolerated in the environment? Are the social and economic costs of control justified by the risks? Judgments must be made in answering these questions. These judgments often are not purely scientific, but are political in nature.

It is obvious that the scientist has a place in providing input to this judgmental process through reporting the results of his work, hopefully with appropriate caveats. Most of us feel that we have discharged our professional responsibility when we have presented the results of our work to the environmental-policy formulator. We are then all too eager to back off and let the policy makers and regulation formulators go about their business. These decision makers, in turn, are perhaps very pleased to have the scientist, with his cautions concerning the interpretation of his work, out of their hair.

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As this paper concerns statistics and environmental law, perhaps "statistics" should be defined. A popular dictionary¹⁾ contains three definitions:

1. "The mathematics of the collection, organization, and interpretation of numerical data; especially, the analysis of population characteristics by inference from sampling..."
2. "A collection of numerical data..."
3. "Political science dealing with state affairs..."

It is this third definition which is the major topic of discussion. The first definition, however, should also be considered as it clearly states that statistics is a branch of mathematics. Indeed the same dictionary¹⁾ defines "statistician" as "A mathematician specializing in statistics."

The use of language in mathematics is, or should be, precise. It would be reasonable, then, to expect at least as much care in the use of the language of statistics as in the use of mathematical language. Such care would be expected particularly of the law, which often focuses on the interpretation of language. Some would even declare that greater care was essential in the use of statistical terminology because statistical terminology must often deal with uncertainty and inductive inference.

Consider, now, the language used in the specification of the limitations for the average of daily water effluent contaminant values for any period of thirty (30) consecutive days. First, consider the limitations for the nitrogen fertilizer industry. It can be inferred from comments (14) and (22) on page 12834 of the April 8, 1974, Federal Register that these limitations represent, in fact, the average discharge attained by exemplary plants within each category or subcategory. Quoting the last sentence of comment (14)

"Limitations for ammonium nitrate, therefore, have been revised to the average of the best levels currently being achieved by plants not using ion exchange."

Quoting from comment (22)

"Congress, in the Agency's view, intended that the best practicable control technology currently available be determined by reference to the average of the best existing performances by plants of various sizes, ages, and unit processes within each industrial category. This average is to be based not on a broad range of plants but on the performance levels attained by exemplary plants within each category or subcategory."

A similar statement for the iron and steel industry can be found in Section iii of the proposed rules given on page 6492 of the February 19, 1974, Federal Register.

"The unit effluent load limitations were developed by determining the minimum unit effluent volumes that could be achieved by the application of good water use practices and by a determination of residual pollutant concentrations that remain after application of the appropriate treatment technologies. The product of these is the unit effluent load limitations proposed. The limitations thus developed represent values not to be exceeded by any thirty (30) consecutive days average..."

It is a fundamental concept that average values being calculated from measurements having a distribution can be expected to have a distribution also. The conceptual population of averages has as the true average of its distribution the true average of the distribution of the original measurements. The variability of the averages is reduced from the variability of the original measurements in proportion to the square root of the number of measurements averaged.

In each case it is assumed that if an operator installs the best practicable control technology currently available and operates it properly, then the average of daily discharge measurements for every period of thirty (30) consecutive days will be the same. Ignored in the statement of these regulations is the fact that the average of the daily discharge measurements for a period of thirty (30) consecutive days is an estimate of the true average performance of the facility and, therefore, exhibits some variability. The operator is then left with a 50 percent risk of violation.

Dr. J. Stuart Hunter has, during his work on the environmental measurement problem, uncovered many other examples. Dr. Hunter stated the following examples during his presentation to the American Statistical Association.²⁾

"Consider the description of the EPA reference methods for the criteria air pollutants that appears in the Federal Register, Title 40, Appendix A 4. We read under the caption 'Precision, Accuracy, and Stability' for SO₂ (36FR8188), the following, 'Relative standard deviation at the 95 percent confidence level is 4.6 percent for the analytical procedure using standard samples...' We can interpret 'relative standard deviation' to mean the coefficient of variation, but the phrase 'at the 95 percent confidence level' is simply undecipherable: Too many interpretations are possible. In an attempt to unfold the meaning of this statement, the literature referenced in the Federal Register was checked only to discover that the estimate of the 'relative standard deviation' had been based on three observations(!). The statistical statement in the Register is not only unclear, it is based upon sketchy information. Continuing in the same issue of the Register, under the caption, 'Precision and Accuracy,' we find the following:

On Suspended Particulates

'4.1 Based upon collaborative testing, the relative standard deviation (coefficient of variation) for single analyst variations (repeatability of the method) is 3.0 percent.'

On CO:

'4.1 Precision is ± 0.5 percent full scale with 0 to 58 mg/m³ range.'

and again later under definitions:

'Precision: The degree of agreement between repeated measurements of the same concentration, expressed as the average deviation of the single result from the mean.'

On Photochemical Oxidants:

'4.1 The average deviation from the mean of repeated single measurements does not exceed 5 percent of the mean of the measurement.'

On Hydrocarbons:

'4.1 Precision determined with calibration gases is ± 0.5 percent of full scale in the higher, atmospheric analysis ranges.'

Thus, for each criteria air pollutant we have unique measures of precision.

Or consider the following nonsequitor from the Federal Register, 10 September 1976 under fuel economy testing; calculation and exhaust emissions test procedures for 1977-1979 model year automobiles, Interim Final Rule Making and Proposed Rule Making:

'Unlike statistical approaches to sampling, representative sampling plans rely on the testing of enough cars within each base level so that the fuel economy of production vehicles within each base level is adequately represented by the vehicle tested.'

As Professor Deming has stated, the paragraph begins by scorning statistical sampling, and then proceeds to describe a stratified sampling plan. It would appear that no knowledge of statistics is required before the language of the art is employed."

Thus the language, which should result from definition 1, does not appear in resulting official regulations and procedural descriptions. Why is this the case? Is it because the practioners of statistics have themselves ignored the implications of definition 3? Or, is it because the lawmakers do not think it is necessary to heed the pronouncements of the statistician because they are perceived as irrelevant to the lawmaking process? Perhaps the answer is a combination of the two.

As lawyers want to look for precedents, let us briefly consider whether there are precedents for a close association between science and the law. When I attended the 1976 annual meeting of the Natural Resources Law Section of the American Bar Association as a technical observer, along with an EPA statistician, we heard topics concerning environmental law discussed with great interest and gusto. However, nowhere in the discussions was the importance of the quality or quantity of technical input considered. Is it then that technical and scientific input has no place?

Lee Loevinger in his concise paper, "Jurimetrics: Science in Law,"³⁾ indicates that the use of science in seeking answers to social and legal problems has long been urged by eminent scientists and lawyers alike. Karl Pearson,⁴⁾ writing in 1892, expressed the spirit of his age as follows:

"The classification of facts and the formation of absolute judgments upon the basis of this classification—judgments independent of the idiosyncracies of the individual mind—essentially sum up the aim and method of modern science. The scientific man has above all things to strive at self-elimination in his judgments, to provide an argument which is as true for each individual mind as for his own. The classification of facts, the recognition of their sequence and relative significance is the function of science, and the habit of forming a judgment upon these facts unbiased by personal feeling is characteristic of what may be termed the scientific frame of mind. The scientific method of examining facts is not peculiar to one class of phenomena and to one class of workers; it is applicable to social as well as to physical problems, and we must carefully guard ourselves against supposing that

the scientific frame of mind is a peculiarity of the professional scientist."

The same views were expressed by the great lawyer and jurist, Oliver Wendell Holmes,⁵⁾ in 1895 when he said

"An ideal system of law should draw its postulates and legislative justifications from science. As it is now, we rely upon tradition, or vague sentiment, or the fact that we never thought of any other way of doing things, as our only warrant for rules which we enforce with as much confidence as if they embodied revealed wisdom."

Holmes^{6,7)} reiterated this theme more than once, and he spoke for a school and a generation of legal realists when he declared

"For the rational study of the law the black-letter man may be the man of the present, but the man of the future is the man of statistics and the master of economics."

"...The growth of education is an increase in the knowledge of measure. To use words familiar to logic and to science, it is a substitution of quantitative for qualitative judgments...In the law we only occasionally can reach an absolutely final and quantitative determination, because the worth of the competing social ends which respectively solicit a judgment for the plaintiff or the defendant cannot be reduced to number and accurately fixed. The worth, that is, the intensity of the competing desires, varies with the varying ideal of the time, and, if the desires were constant, we could not get beyond a relative decision that one was greater and one was less. But it is of the essence of improvement that we should be as accurate as we can.

"...I have had in mind an ultimate dependence upon science because it is finally for science to determine, so far as it can, the relative worth of our different social ends, and, as I have tried to hint, it is our estimate of the proportion between these, now often blind and unconscious, that leads us to insist upon and to enlarge the sphere of one principle and to allow another gradually to dwindle into atrophy. Very likely it may be that with all the help that statistics and every modern appliance can bring us, there never will be a commonwealth in which science is everywhere supreme. But it is an ideal, and without ideals what is life worth?"

This view that science and law have a close relationship and that science must contribute to the formulation of law continues to be expressed. However, as C. P. Snow⁸⁾ admits, "it is not always easy to know which scientist to trust." This points to a problem perhaps more important than that of language. A scientist who is a zealot is no different from anyone else who is a zealot. Often, for each "scientist" expressing a point of view, another can be found who will express with equal zeal the opposite point of view, with both opinions based on the same data. Perhaps worse than the zealot scientist are those who for reasons of increasing their list of publications, continue to turn out reports of questionable value under the guise of scientific papers.

As scientists concerned about quality environmental regulation, what can we do to have the maximum impact on these regulations? First, we must gain a better understanding of the political processes through which society makes its decisions and take a much greater interest in these processes. We cannot stand back after making our scientific pronouncements and let the politician take over. We must assume our responsibility as practitioners of statistics which is inherent in the

third definition. That is the responsibility for insisting on quality, responsibility for curbing misuse, responsibility for adequate description and for stressing limitations. We must insist that these responsibilities be met by all practitioners as well.

Second, we must work toward better communication and appreciation of statistical concepts with the lawmakers. This will help to overcome the language barrier. The result will be better standards and more reasonable regulations.

And lastly, we must, through our professional associations, become more active in expressing our opinions. By speaking out as an association of professionals the real or imagined advocacy bias can be avoided. Professional associations must also make their views known to the lawmakers in the course of public hearings, or perhaps through lobbying. The American Society for Quality Control is currently doing this in the area of consumer product standards. This activity must be expanded to other areas as well.

The need for scientific knowledge in policy-making institutions is increasing at an increasing rate. Scientific data are clearly not only relevant but crucial to the consideration of many of our most pressing contemporary social problems.

The Government has been rapidly increasing its scientific manpower, particularly in the environmental area. Before we take comfort in this, note the following caution from Loewinger's article.³⁾

"When science becomes a part of government, it is the science that is corrupted, not the government that is ennobled. As a speaker at the 1971 AAAS annual meeting pointed out;

'To the extent that the scientific enterprise becomes enmeshed in this (governmental) network, its critical distance is diminished. Independent, critical work is dampened and impeded where there exist obligations or close connections to those in power. What this means is that one cannot serve two masters—at least, not at the same time. A commitment to theorizing, for example, precludes involvement in the practical world of policy-making.'"

In a democracy, the most appropriate and promising method for incorporating scientific knowledge into public law is public dialogue. If we as professionals do not take the opportunity to provide quality input to the policy-making system, then the void will be filled by others who are perhaps less concerned with such quality.

It is understood that the material in this paper is intended for general information only and should not be used in relation to any specific application without independent examination and verification of its applicability and suitability by professionally qualified personnel. Those making use thereof or relying thereon assume all risk and liability arising from such use or reliance.

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LCS 020:10:000

QUALITY COSTS - WHAT DOES MANAGEMENT EXPECT?

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INTRODUCTION

The measurement of quality cost has proven its importance in the quality control field (1). However, my experience indicates that only about 40% of the American companies have a system that goes beyond measuring scrap and rework dollars. Furthermore, some companies do not even dollarize scrap and rework. Thus, for many companies quality costs still represent an opportunity.

One of the factors influencing the introduction of a quality cost system in a company is the attitude of top management. This paper will look at quality costs from the viewpoint of upper management levels--plant manager to president. This will be done by describing ten actual situations ("scenarios") and offering some conclusions for each.

SCENARIO #1 - WHAT ARE QUALITY COSTS?

A quality control manager decides to measure quality costs. He works with the accounting department and proposes that quality costs be compiled for four basic categories: prevention, appraisal, internal failure and external failures. The accounting people declare that they certainly want to cooperate with him but "the books aren't kept that way." They also point out that scrap and rework dollars have long been known and are rather stable at about 2% of direct labor and direct material costs. As the 2% is included in the standard cost system, the accounting people feel that scrap and rework costs are covered and there is no need for further measurement.

Finally, the data is collected and presented to the plant manager. His initial reaction is "these are the costs of the quality control department and they certainly are too high." This misunderstanding horrifies the QC manager. Next, the manufacturing manager refutes the data because he claims that part of the "scrap" is unique to the type of manufacturing process and clearly unavoidable. Meanwhile, the accounting people continue to emphasize the inclusion of scrap and rework dollars in standard costs. The plant manager is confused.

Conclusions. Top management expects that any presentation of quality costs will clearly identify the meaning of the costs. Further, they expect that any arguments about including certain elements of costs such as unavoidable manufacturing scrap will be settled before presenting the final report. The misunderstanding that quality costs are the same as the costs of the quality control department is an offshoot of the idea that the quality program in a company is the same as the work of the quality control department. We know that this is not the case but, like it or not, many people believe it. It's probably too late to change the term quality cost but you may want to consider using another term in your own company.

We need to say what quality cost is and what quality cost is not. Quality cost is a collection of costs throughout the entire company associated with the prevention, generation, measurement, and correction of quality problems. Quality costs are not equal to the costs of the quality control department just as federal expenses are not equal to the expenses of the Treasury Department. Quality costs go beyond the standard amount for scrap and rework included in standard costs. However, the standard cost system assumes that such costs are inevitable--the QC system views these costs as cost reduction opportunities.

Avoidable and unavoidable costs in connection with quality should be clearly labeled. In addition, careful explanation is needed for any "hidden costs." For example, suppose a packaged product must meet a minimum weight requirement. If the process variability is wide then the process average must be set sufficiently above the minimum weight to have a high probability of meeting the minimum on individual packages. Although the product meets the specification, the high process average represents a giveaway which is a hidden cost of quality.

SCENARIO #2 - PAR

A QC manager presents his first quality cost study and shows that quality costs are equal to 11% of sales dollars. There is general agreement by upper management that the figure is high but top management asks "what should it be?" The QC manager replies that it is difficult to have a specific numerical answer but the industry average is about 6%--he read this in a magazine article. Now the arguments begin. Someone points out that the 6% probably varies by type of industry. Another argument is that the amount of quality cost depends on the quality philosophy of the company--is the company aiming to be the top quality leader or just average with competition? Another question is how different companies define quality costs--is overhead included, is unavoidable manufacturing scrap included, are periodic losses of new contracts due to poor quality image included? These questions are a mixture of wind, snow, ice, and trouble.

Conclusions. Management not only wants to know the total quality cost but needs to know how to interpret the total. Comparison to other companies or industry in general can be dangerous for the reasons cited.

A better tact is this: select a few major projects to improve, dollarize the size of the quality costs on these projects, set a cost reduction goal, estimate the investment required and calculate a measure of effectiveness such as return on investment or payback period. Of course, the complete participation of responsible departments in all this is a must.

Finally, trends may be more important than the absolute value of quality cost. They can serve as an early warning device and help to set specific goals for the future.

SCENARIO #3 - WHAT SHOULD I DO?

The QC manager of a consumer product presents a quality cost report including the four basic categories. The executive vice-president reviews it and agrees that the overall costs are high and that the categories make good reading but then nothing happens. Finally, he asks "what should I do with this information?"

In another plant making a product that is a rental product, the quality cost report to management is extremely detailed. Many ratios highly useful to QC professionals are presented and the emphasis is both on investment costs and losses. Again, the quality cost report simply is not getting enough action from upper management.

In two other cases, upper management express a desire to relate quality costs to objectives for functional managers, e.g., through a tie-in to bonus plans or a management by objectives program.

Conclusions. Management expects to be shown how to interpret a quality cost report and the benefits and costs of alternative actions. QC measures quality. This scorekeeping is necessary but management expects somebody to show them how to win the pennant. Specific improvement projects with numerical objectives must be defined as part of the proposed action to be taken. This is in contrast to just dramatizing the high total and asking for general support across the board on quality.

The improvement projects can be on products or on tasks within a quality program. For example, objectives for next year on specific products might be "quality costs for the company shall be reduced by 20%"

or the "average leak rate for product x shall be reduced to 4%." Examples of objectives for tasks rather than products might be "quality costs shall be determined for at least one product" or "numerical reliability and maintainability objectives shall be defined for at least one product."

SCENARIO #4 - THE TOTAL

A QC manager calculates quality costs as a total of \$1.5 million for a plant with about 1,000 production workers. The cost is primarily scrap, rework, and warranty charges. He presents this information to justify his request for an increased budget next year.

The plant manager reacts by agreeing that it is useful to collect all of the costs concerning quality across all departments and show it in one total. He agrees that the total is high but says that their product is relatively expensive and perhaps the absolute figure is not completely meaningful. After reviewing the literature, the QC manager restates the quality costs as 9.2% of the sales income and shows a breakdown of the total into the usual four basic quality cost categories. There is much argument about the usefulness of all this for the top management people. (The president later told me that he did not recall ever hearing about the four categories--zero impact.)

Conclusions. The total quality cost figure is often dramatically high. However, presenting this figure by itself to top management people generally is not sufficient. The figure must be related to sales or some other base and some breakdown of the figure should be made. The problem is that the nature of the breakdown often depends on the industry and on the specific management person involved (see Scenarios 5, 6, and 7). Useful as the prevention, appraisal and failure categories are they may not be the right categories for your case.

It may help to distinguish between fixed and variable quality costs. Other possible breakdowns are by product, vendor, department defect type or defect cause depending on the level of detail desired. Pareto scores again.

Finally, quality cost information may need to be presented as part of a larger "instrument panel" which shows quality costs plus other quality indicators that can help management understand the significance of the dollar figures. The quality indicators used for top management of an equipment manufacturer are shown in Table 1:

TABLE I. Example of Quality Indicators

Internal quality indicators

1. Machine shop scrap and rework hours
2. Assembly scrap and rework hours
3. % of finished product which is incomplete at end of line
4. Dollars of purchased material rejected

External quality indicators

1. Defects found on delivery to dealers
 2. Failure incidents per unit time
 3. User rating of product based on opinion poll
 4. Dollars of warranty expense
-

Each of these indicators is related to an appropriate base. Note that only 2 of the 8 indicators are in dollars. The primary reason is that a large share of the quality costs are in labor hours and this governs the emphasis on quality improvement.

SCENARIO #5 - UNITS, UNITS, UNITS

A group of QC managers are comparing notes on their experiences with quality cost. Bill comes from a chemical company and mentions how his division president calculated the cost of spoilage as 13¢ per share of stock outstanding. This was instrumental in convincing the president to direct corporate QC to set up a quality cost system throughout the division.

Tom comes from a mechanically oriented company where the quality cost for all divisions is \$76 million per year. He comments about the value of converting this dollar figure into equivalent physical terms. For his case, the \$76 million converts to 5,900 extra personnel, 1.1 million square feet of space, and \$6 million of extra inventory being carried. These figures collectively are equivalent to the entire yearly production of one plant of his company. This physical analogy had great impact on his management.

Ed works for a food processing plant where rework alone is three-quarters of a million dollars a year. This figure was instrumental in convincing the plant manager to set up the training program for foremen in process control methods. In this case the effect on delivery promises to customers was also an important factor in dramatizing the importance of the rework problem.

Conclusions. Management expects us to present quality costs in a language suited to their needs. Often that language is dollars but not always. Sometimes productivity and delivery schedules or other matters are equally or more important. The need is to discover what language fits the territory.

SCENARIO #6 - BASE, BASE, BASE

The QC manager of a company that designs and manufactures mechanical assemblies prepares a quality cost study and explains the results to engineering, manufacturing, purchasing, and other major function areas.

Everyone is impressed that the total quality cost is high but there is considerable difference of opinion on how to interpret the figure. A further discussion breaks down the total by plants but now the arguments really become heated. The different plants make different products and the only agreement reached is that the absolute quality cost dollar figure is not sufficient to make comparison between plants.

A number of different bases are proposed such as expressing quality cost as percent of sales, quality cost as percent of factory costs, and so forth and the discussion continues into the night.

Conclusions. Management expects the QC manager (in cooperation with others) to determine the most useful way to present quality cost figures. The literature emphasizes quality cost as percent of sales. However, other bases include direct labor hours, direct labor dollars, standard manufacturing cost dollars, value added dollars, burden, and product units.

It is difficult to logically determine beforehand which base or bases to use. In my experience, several bases should be selected and tried for a period of time and then a judgment made on which bases are best.

Figure 1 shows total quality costs expressed in absolute dollars and two different bases. Note how the conclusions vary with the base used. The data for this figure was taken from Reference 2 which includes a further discussion of bases.

SCENARIO #7 - MY PLANT IS DIFFERENT

In my experience, the reaction of plant managers and company presidents concerning quality cost is quite varied. The president of an electrical component manufacturer is oriented to meeting the needs of the appliance industry and focuses on quality and sales income rather than quality and cost reduction. On the other hand, the president of a pharmaceutical company wants to control the cost of quality but is more concerned about the seriousness of a major recall on any of his products. The division manager of an appliance firm is more concerned about the customer getting value than he is about reducing quality costs. The president of a small firm producing lawn equipment echos the same belief. The plant manager of a chemical company explains that a directive from corporate headquarters set the stage for him: reduce the cost of

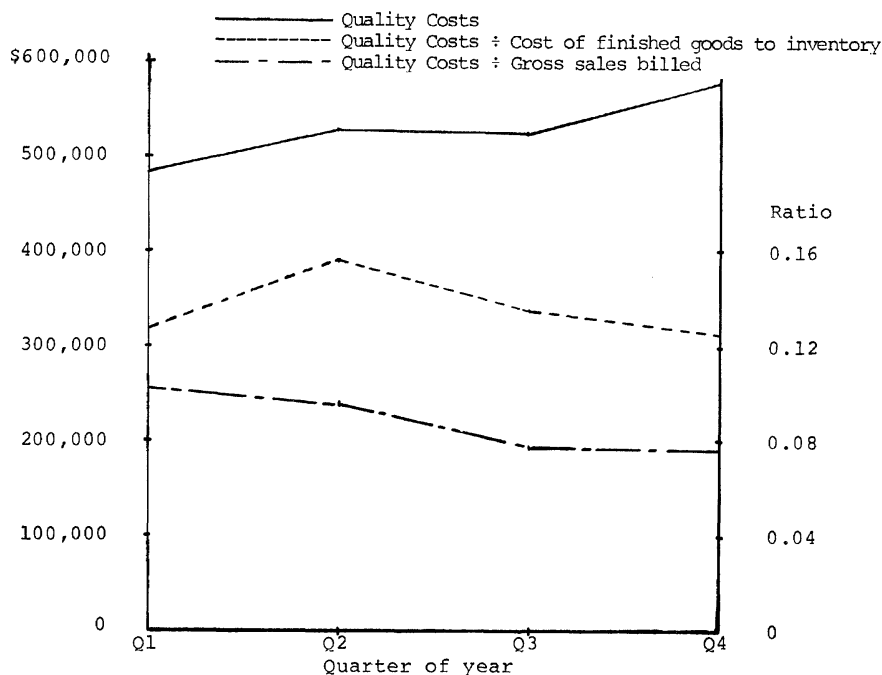


FIGURE 1. Quality Costs Using Several Bases.

nonconforming material. A vice-president of a high technology company is cost/benefit oriented. In his words: "I don't mind spending money for quality but I sure wish I could be more certain of my investment rather than spend it in a defensive manner."

Conclusions. Management expects us to present quality costs in a way that is unique for their situation rather than emphasizing the conventional methodology of quality costs. If the orientation is toward reducing the cost of nonconformance, the conventional methodology will meet the test. Other priorities require a different tact.

The priorities of the executive depend on the industry but also the scope of the responsibility. For example, a plant manager responsible only for manufacturing may stress conformance to specifications. A division or company president with broader responsibilities must weigh the cost of nonconformance with design, sales and other matters influencing profit.

SCENARIO #8 - VALUE

A discussion with a division manager for a major product line in the appliance industry makes it clear that his road to increased profits is to increase sales rather than just reduce quality costs. He feels that product value is the key to increased sales. For example, his company can provide a digital readout of temperature in the main compartment of a refrigerator for about \$40 additional in the price. However, a study concludes this would be poor value from the customer's viewpoint and therefore the idea is dropped.

The same manager also makes a distinction between the real and perceived performance of the product. The real performance of the product is what the product can actually do. The perceived performance is the performance as the customer sees it. For example, refrigerators are designed to have a certain temperature in the refrigeration compartment. If hostile environments are encountered (high humidity, high usage due

This division manager reacts to questions about quality cost by directly orienting to value provided to the customer. This is not the intent of quality cost systems but it is his orientation.

Table 2 shows an example of a method for comparing alternative designs of a product taking into account both performance and cost (i.e., value). For each performance factor a fraction is calculated. The numerator is a product of a weighting constant for the factor and the score achieved by the specific design for that factor. The denominator is the unit cost of achieving the factor by the specific design. Design B shows

Performance Factor	Design B	Design G
Grinding time	9/0.87 = 10.3	6/2.40 = 2.8
Fineness of grind	4/7.82 = 0.5	4/11.88 = 0.3
Frequency of jamming	9/1.98 = 4.6	9/2.46 = 3.7
Noise	4/0.45 = 8.9	4/0.52 = 7.7
Self-cleaning	2/0.49 = 4.1	4/0.58 = 6.9
Elec. safety	16/0.52 = 30.8	16/0.43 = 37.2
Particle protection	6/0.30 = 20.0	2/0.37 = 5.4
Ease of servicing	4/0.52 = 7.7	6/0.98 = 6.1
Cutter life	9/0.83 = 10.8	9/1.32 = 6.8
Ease of installation	9/0.33 = 27.3	9/0.70 = 11.8
Total	72/14.11 = 5.1	69/21.44 = 3.2

Conventional quality costs measure costs incurred by the manufacturer. This is separate from costs incurred by the user of the product (see Reference 3) which in turn is related to income. Although the quality cost concept has proven its use as a cost reduction measure, management may increasingly look to the QC manager to relate quality and sales income. For example, in both the automotive and appliance industries, the share of the market given to suppliers for certain companies directly depends on a quantitative quality rating which is computed periodically. Suppliers whose quality rating is higher than competition are given a higher share of the market for the next purchasing period.

SCENARIO #9 - LET'S NOT GET BURNED AGAIN

HURT IMPROVING

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Management said "let's not get burned again." Some new reliability efforts were instituted including the prediction of warranty costs as early as possible upon the introduction of a new product.

Ironically, management now notes two payoffs: potential field problems are anticipated and the prevention efforts have resulted in cost reduction. The original emphasis was to "get the customer off our back" but (pleasant surprise) this has been accomplished and a cost reduction also achieved.

Conclusions. Particularly for companies making a diversity of new products, upper management expects the quality function to provide early warning devices on warranty costs and other quality related matters. These early warning devices must provide sufficient reaction time to prevent major field quality problems from occurring and to do this early enough to eliminate the need for compromising either costs or delivery schedules. Weibull Probability Paper for warranty cost analysis can be helpful.

SCENARIO #10 - THE CORPORATE ROLE

The president of a major division of a chemical company decides on the need for a quality cost system throughout his division and instructs the division QC people to proceed. The division QC people develop the system and are currently running a pilot run of the system in one plant. So far, the results look encouraging--the necessary data can be collected in a reasonable time. A meeting on quality costs is held at another plant of the division and that discussion raises all kinds of questions. For example, the meaning of manufacturing scrap, avoidable vs unavoidable costs, who is responsible for publishing the data, exactly what format will the data be in, what use will be made of the data by plants, and more.

Conclusions. Management often looks to corporate QC people to develop and institute an overall quality cost system for the company. However, management knows that reductions in quality costs come from plant cafeterias rather than corporate dining rooms. Thus, the corporate people must work closely with the individual plants to develop the quality cost system. Before procedures are issued, sufficient time should be allotted for extensive discussions with the plants to make sure that the plants can provide the data, and that the resulting reports will be useful both for comparing the different plants and for conducting the quality improvement programs. Along with this should be the realization that the issuance of the reports alone will not secure a lasting reduction in quality costs. Large quality costs should be used to justify and provide to the plants the additional manpower needed to determine the causes of the quality problems and institute corrective action.

SUMMARY

The determination of quality costs is still unknown in many companies. This presents an opportunity for the QC manager. However, the priorities of top management are quite varied even though the profit objective is common. The challenge for the QC manager is this: view quality as a business problem and adapt conventional quality cost methodology to meet overall company needs.

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LCS353:10:000

CAD/CAM - QUALITY'S MOST SERIOUS CHALLENGE

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INTRODUCTION

Within the past two decades, the degree of advancement in the machined parts industry has been only one step short of miraculous. Today, with the aid of computer technology and other related technical advances, an idea can be translated from the mind of the designer to a finished machined part without one single piece of paperwork being created. Furthermore, the design and production phases are being accomplished at a fraction of the time previously required by conventional means. Mathematical calculations and machining cycles are performed by computers, thus reducing the chance for human error.

One cloud hangs over this otherwise bright picture. This is the heretofore inability of the quality assurance discipline to maintain pace with the rapidly accelerating design and machine tool advancements. Traditional inspection methods will result in either an excessive amount of machine idle time for verification activities, or an abnormally large amount of scrap and rework when errors are not detected until final inspection is performed. Quality Assurance activities must, therefore, be designed to take advantage of these technological advances, yet provide for the earliest discrepancy definition and correction activities possible, based upon economic considerations.

The purpose of this paper is twofold: First, it will acquaint the reader with the development of the numerical control (N/C) discipline, beginning with the early attempts, progressing through the various stages of development and ending with projections for future evolutions.

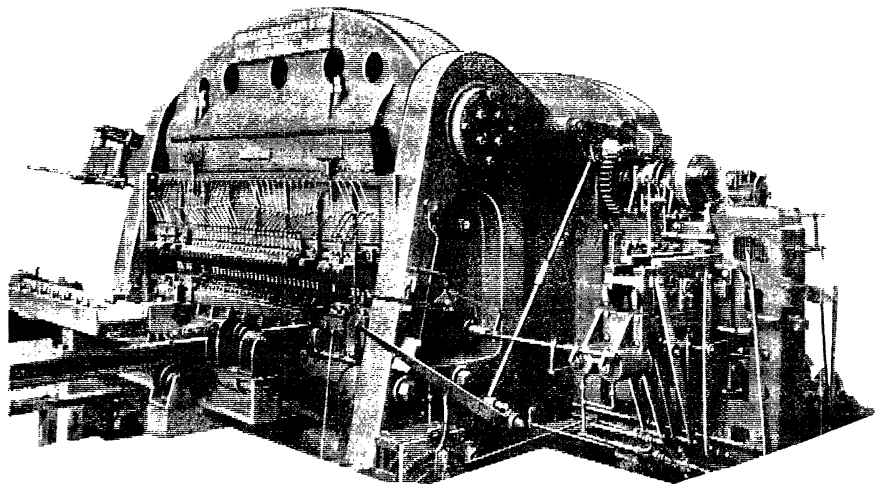
Secondly, the need for a revision in quality assurance discipline to control this new science will be emphasized. Since the concept of verification after machining is no longer economically feasible, verification activities must be advanced into the software portion of the program. Basic guidelines with viable alternatives will be discussed, with the final solutions left up to the discretion of quality management.

THE BEGINNING OF NUMERICAL CONTROL

William Sellers, President of William Sellers & Company of Philadelphia, is credited with developing the first successful numerical controlled metalworking machine. Before his death in 1905, Sellers had outfitted a large multiple punching machine with a punched paper tape control unit. This machine was used to produce prefabricated bridge and other large structural forms at the Midvale Steel Company. Work continued on the development of this concept by the Sellers Company and in 1906, a large, pneumatically controlled 36 tool punching machine was placed on the market. With a capacity to handle steel plate 10 ft. wide and up to 100 ft. long, the machine would automatically punch rivet holes and other openings at predetermined spacings after receiving commands from its pneumatically operated punched card reader.

Partially due to its size and mainly due to industry's preference for cam-controlled machinery as a means for automation, the Sellers automatic punch press was never a strong commercial success and was subsequently abandoned.

In 1921, the second attempt to introduce a numerical controlled machine was made by Emanuel Scheyer. By adaptation of a control unit



WILLIAM SELLERS & CO's 1906 MODEL TAPE CONTROLLED PUNCHING MACHINE

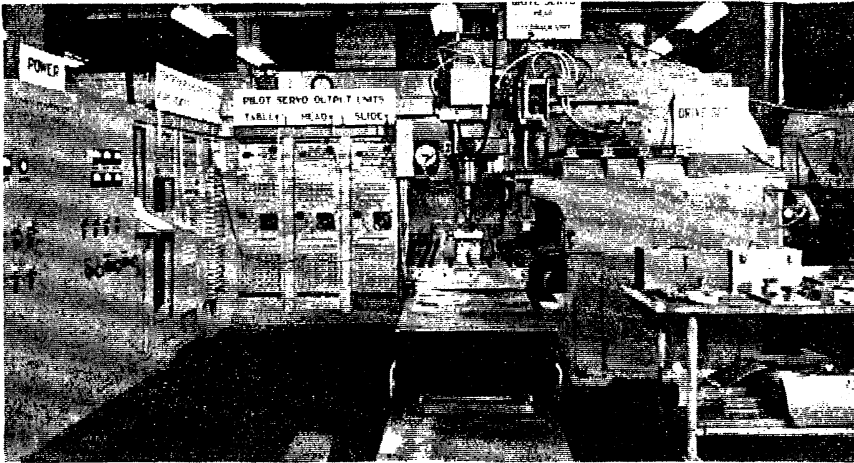
principle perfected by Joseph Marie Jacquard. Scheyer designed the first numerical controlled lathe. This rudimentary machine consisted of a bewildering accumulation of "gears, clutches, levers, and pneumatic cylinders to operate the cross slide and carriage as well as their feeds, traverse rates, and the spindle speed". Recognizing that this new concept could not actively compete with the more popular cam-operated machines, Scheyer designed his lathe for "handling work which is larger or more complicated than can be handled by cam-controlled machines." Like so many other ideas ahead of their time, Scheyer's N.C. Lathe soon dropped from view.

THE BIRTH OF THE NC ERA

By 1948, the Parsons Corporation of Traverse City, Michigan, had developed a system for producing helicopter blade templates from numerical coordinate data. By calculating airfoil coordinates on an IBM 602A multiplier and feeding these data points into a Swiss jig borer, the tedious task of laying out the job manually had been eliminated. In 1948, John Parsons saw the drawings for a new design concept of integrally stiffened skins that had been developed by Engineers of the Lockheed Aircraft Corporation. In place of stringers, ribs and a skin being riveted together to form an assembly, the design called for single-unit structure consisting of a contoured outer surface with a series of pockets being milled on the inner surface. The material left between the pockets would serve as the stiffening webs. After reviewing the design, Parsons conceived the idea of machining this part by reducing the design to a series of coordinate commands, feeding these coordinate commands onto a punched card, and controlling a milling machine by the punched cards. The Air Force became interested in this new concept of machining and, after evaluating demonstrations of a similar application at the Parsons Corp. and the Snyder Corporation in Detroit, awarded a contract on June 15, 1949, to study its feasibility. From this beginning the NC Industry was born.

In the Servomechanism Laboratories at MIT, a 28-inch Cincinnati Hydro-Tel milling machine was selected as the machine to be used in the study. The machine was extensively modified, including replacement of the table, cross-slide and head drives with variable speed hydraulic transmissions capable of being controlled by electrical impulses. By 1953, sufficient data had been obtained to indicate the practical application of the NC approach. A detailed 24-page report on the results of this study appeared in the American Machinist Magazine on October 25, 1954 and started a flurry of development activity within the industry.

By the end of 1955, a full compliment of NC machines, including 5-axis mills, drills, jig borers and lathes were on the market. Added incentive was given to the development of NC machines when the Air Force placed an order for 100 of the new contour-milling machines. Four companies were selected to build the machines and five companies were selected to build the readers.



MILLING MACHINE SET UP IN SERVOMECHANISM LAB AT MIT

With a full compliment of machines in the NC field, interest now turned to improvements. By 1957, automatic tool changing was offered by the Barnes Drill Company on one of their drills. IBM and Fostick Machine Tool Company developed and introduced a tape-controlled jig-borer with an automatic tool changer in 1958. Also in 1958, Kerney & Trecker developed a flexible automatic machining line for Hughes Aircraft. In the line, a drill, mill and jig bore were tied together and operated by a single, tape controlled reader. This unit was known as the Milwaukee-Matic Model I.

The Milwaukee-Matic II was introduced later that year and made everything else look awkward. The work was mounted on an indexing table so that four sides of the part could be machined without relocation. A rotary drum mounted on the side of the machine held up to thirty different tools that would automatically be selected by tape command. By combining the functions of boring, drilling, milling, and tapping with the four-sided machining capability, the multifunction, or machining center was born.

Initially, the NC machines received their commands from punched paper cards (IBM Cards). This method was replaced before long, however, by the punched paper tape. Two variables made this move a logical one. First, the tape was understandable, convenient and worked relatively well in a hostile environment. Secondly, tape preparation equipment, such as the Friden Flexowriter was already in use and readily available, due to its demand in other business and accounting operations. As NC technology advanced, the taped programs became longer and the tape reader speeds kept going higher, thus creating a need for a more durable and reliable medium than that offered by the paper tape. The introduction of Mylar-based, or laminated tape satisfied this need for durability, but created another problem. Punching the Mylar tapes taxed the design limits of the flexowriter, resulting in increased maintenance for punch pin replacement and adjustments due to improper tape registration.

ENTER THE COMPUTER

The computer was first introduced into the market place as an account-

ing tool. With an assist from the Air Force in the form of a development contract, this new science was expanded to include NC tape programming capabilities. Computer assisted programming was introduced and grew rapidly in the late 1960's and early 1970's with many companies offering computer time sharing and special programs to assist in NC tape preparation.

As the state-of-the-art was advanced in computers, the flexowriter became obsolete as a business and accounting tool. The NC market was not yet large enough to justify continued production so it was discontinued. Microprocessor technology had been developed sufficiently by this time, however, to allow the creation of a smart terminal specifically designed and dedicated to the generation of NC tapes. Although improvements have been added, the basic design initially offered by companies such as Numeridex is the most widely accepted method of NC tape preparation.

The first attempts at controlling the NC machine directly from the computer were made in the middle 1960's. However, the early vacuum tube computers were incapable of providing sufficient speed and versatility to make this application economical. DNC (Direct Computer Controlled N/C machining) gained a small measure of success only in a hand full of companies whose production rates justified it.

As the computer technology advanced, aided by rapid advancements within the electronics industry, computers became smaller and less expensive. Response times and data assimilation capabilities were also improved. By equipping a microprocessor with a memory and input/output circuitry, a microcomputer, small enough to include on a NC machine is obtained. Presently, this system of machine control is becoming the most prominent in the NC field. Known as CNC, the machine receives its coordinate commands from a program stored in its integral computer. Permanent storage of the machining programs is provided in a main, or parent computer and are fed to the machine upon demand.

Appearing on the horizon is yet another generation of NC machine capable of writing its own programs, known as PNC (programmable numerical Control). The machine can be equipped to either punch a tape or write a computerized program while the first part is being machined by operator-controlled moves. Further, advantages include the ability to correct, or modify existing programs at the machine.

COMPUTER GRAPHICS

With the advent of computer graphic capabilities, the time required to develop and draw the design of a part has been reduced to a fraction of the time required before. By utilizing mathematical calculations previously programmed, the designer is able to complete his "drawings" on a scope and immediately send it to computer storage. When paper drawings (blueprints) are required, they may be obtained from a computer controlled printer. When change to the design become necessary, the design may be recalled to the scope, the changes made, and design re-entered into the computer's storage bank. Utilizing this system, there should be little chance for obsolete drawings to be present on the manufacturing floor.

Manufacturing planning activities also enjoy the benefit of increased accuracy and time savings by use of interactive graphics. The planner may call the design up on the screen and progressively plan the manufacturing steps in reverse order of fabrication. (Thus, he starts with a finished part and plans back to the starting material configuration). As the machining sequences are being formulated, NC tapes (or programs), holding fixtures and cutter configurations can also be designed and ordered. When the planner is finished, his input can all be stored in the computer memory bank.

Production Control and scheduling activities have also been adapted to computer language quite successfully by a number of companies. With today's computer technology, it is quite conceivable to design, plan,

schedule and manufacture parts without a single piece of paperwork being created. Other programs can be added to order material, accumulate cost data and issue shipping instructions.

THE ROLE OF QUALITY

From the above discussion, it would appear that computer technology has provided almost all of the answers for an efficient manufacturing system. One factor, however, remains unresolved. This is the question of economical, yet efficient product assurance at the customer level. Consumer demands for product safety and reliability considerations have been augmented by government regulations and consumer advocate activities. This results in added pressure on the producer (and especially his Quality Department) to take every reasonable precaution of assuring that only good units of product are offered for sale.

Inspection (i.e. physical measurement of a finished part) is the traditional method of assuring that the parts passed on are within the limits of the design specifications. Before the introduction of NC, one inspector could normally inspect the work of eight machinists with a reasonable degree of accuracy.

Today, one NC machine can perform the work of five to twelve conventional machines, while holding intricate dimensional relationships and tolerance never before attainable. Parts can be produced in a few hours that will require several hundred hours to measure when traditional layout methods are used. Of paramount importance, however, is the fact that inspection only sorts the good from the bad. It does not prevent the defect from occurring.

Quality Control, in its ultimate form, assures that the product meets all previously established requirements and that the process is controlled within specified limits. Again, however, the effectiveness of a quality control system depends upon its ability to measure the product in a timely manner.

American Machinist Magazine describes the science of Quality Assurance as a predictive process. "To be effective, it requires assessment, monitoring, and control. Every process in the manufacturing cycle of a product must first be assessed to determine its potential for meeting previously established quality requirements. Once the process is selected, it must be monitored to make sure that the assessment of its potential is still correct. Finally, the process must be controlled on the basis of such monitoring to keep the process under control." Under the terms of this treatise, every process in the manufacturing cycle must be assessed. This means that Quality must gain the expertise in the computer technology-related manufacturing practices, as well as conventional machining modes, in order to properly assess the manufacturing process currently in effect in the present hybrid machine mix employed by most shops. As more and more computer technology is introduced, this requirement for computer-oriented Quality Engineers will become increasingly acute.

In the last decade, the emphasis of computer technology has been applied to producing the part. Little effort has been made across the industry to provide equipment that will economically measure the product during selected stages of manufacture. As a result, each company has attempted to design their own inspection screens. This has often been accomplished by selective sampling, composite gaging, and reliance on the NC machine to produce a good part. Partially because of the lack of computer technology expertise and principally due to the lack of adequate funding, the quality discipline has lagged behind the accelerated advancement of its production counterpart.

Quality Assurance, as a discipline, must re-examine its position of Product Assurance, especially in the area of machined parts. In high volume, continuous production environments, the use of sample inspections and control chart concepts have proven to be adequate for controlling the

quality of the end product. Process controls have been demonstrated to be successful in the control of heat treatment and chemical process operations. First part inspections, combined with sampling of the finished lot is also a popular means of control. Although these methods have been proven to be successful in the past, their effectiveness in controlling the machining concepts of tomorrow will, at best, be marginal. Consider for a moment these facts:

- o Lot sizes are now less than 50 pieces for 75% of all production runs.
- o 90% of all NC machine programs take less than 27 minutes to run. 48% are run in less than 10 minutes.
- o Rework of part nonconformities are almost non-existent on most NC machines.

Once these facts are examined, in the light of today's Product Assurance programs, it is immediately apparent that additional expertise and measurement capabilities must be obtained. Otherwise, prohibitive scrap and rework costs and excessive inspection bottlenecks will impede the progress of improved machining productivity. The other alternative of relying on the machine's ability to produce only good parts could prove disastrous in light of today's product liability litigations.

A successful quality assurance program for the CAD-CAM concept must begin at the earliest stage of the program -- the design phase. Decisions must be made as to how and where the product will be measured for compliance. Inaccessible dimensional relationships and specification contradiction should be resolved before the manufacturing effort is initiated. Additional measurement equipment and programs that will be required to verify the product can be ordered in advance to assure its availability, when needed. In many companies, modified forms of this program are currently in effect. Most of the evaluations, however, are currently made from a formal blueprint.

In the CAD/CAM era, two new factors must be considered. The blueprint will be a video portrayal on a scope and the machining will be performed in a fraction of the conventional machining time on a computer controlled machine. In order to perform an adequate assessment of the design and develop an effective, yet economical verification program, the Quality man must have sufficient expertise in both computer technology and shop practices.

Since operator compensation cannot be made for such variables as worn lead screws, slack bearings and cutter wear on a NC machine, maintenance and calibration controls are of paramount importance. From experience, we have proven that the desired metallurgical properties can be obtained during heat treatments if we adequately control the furnace and sample the lot of material. These same results can reasonably be expected from an NC machine if adequate evaluations are scheduled in a timely manner. Several factors must be considered in designing such a program. Among the more prevalent areas are the following:

- o Machine Installation : The initial machine installation, levelling and adjustments made must be verified. The use of a laser interferometer to verify the accuracy at a reasonable cost.
- o Periodic Calibration: Periodic calibration checks on a machine will assure that the machine is still capable of maintaining the tolerance allowables of a design. The use of test programs to make a test part with given dimensions approximating all of the machine moves have been used quite successfully. Position checks measured by laser interferometer have also proven adequate.

- o Tooling and Cutter Control: Quality verification of tool holder settings, tool regrind and holding fixtures will provide an additional degree of assurance. Cutter wear studies provide for changing the cutting tool before a nonconformity appears.

Automated inspection equipment is beginning to appear on the market. Computerized coordinate measuring systems are now available that can provide a wealth of analyzed data. Non-contact gaging concepts are being pursued by many companies, among the more notable being United Technologies Research Center (laser diodes), EMR Photo-Electric (Comp Gage System), and Jones and Lamson (Metric Eye). Total system quality control is the goal of Lockheed Missile & Space Company's IPQC System. The ultimate selection of the equipment best suited for each company must be made by the Quality Department. Since each piece of this equipment is expensive and unique, decisions must be based on application, operator familiarization, maintenance and economic considerations.

To further compound the situation are two new innovations: Automatic Adaptive control of machine tools and Group Technology. Under the Adaptive Control concept, the workpiece will be continually monitored and the necessary adjustments to maintain the required accuracy at optimum machining rates are automatically made. Group technology consists of grouping families of similar parts so that they can be produced more efficiently. Quality Assurance inputs during the definition and design stages of both of these programs are necessary to insure a successful implementation.

The building blocks for tomorrow's quality programs must begin to be carefully selected today if we are to be successful tomorrow. This must begin with personnel, not only fully knowledgeable of today's requirements, but also with sufficient knowledge of computer technology-related systems currently under development to maintain pace with manufacturing advancements. Old concepts must be re-evaluated and adjustments be made accordingly.

The computer has provided us a tool with which we can produce goods and services at a fraction of the time previously required. To assure that these goods and services are continually produced in a prescribed manner requires a system of controls and quality assessments. In order to design and maintain this system of controls and quality assessments, a knowledge of the computer technology-related manufacturing principles must be present.

DOES YOUR QUALITY DEPARTMENT HAVE THIS CAPABILITY ?

310:10:439

ASQC-ACCREDITED FOR AMERICAN
NATIONAL STANDARDS

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ABSTRACT

The Standard Committee serves to assure an interface with standard bodies external to ASQC and to establish liaison within ASQC with the Division and Technical Committees, who provide the expertise and manpower required for the design, development and support of an effective standard program.

INTRODUCTION

Accreditation of ASQC as a standards writing organization was announced by the American National Standards Institute on March 14, 1977. This event, while significant in so far as ASQC is concerned, is "just the tip of the iceberg" in terms of the preparatory activities which preceded accreditation.

ASQC management became concerned and involved in society standards activities and direction in 1973, and in recognition of this attention initiated a program of redefinition and change. In broad terms, what was being sought was an expanded participation by the society and its members into a leadership role in the development and promulgation of standards dealing with the assurance sciences.

During this period of evolution, ASQC assumed the responsibility in 1974 for the Secretariat to the ANSI-Z1 Committee on Quality Assurance. This assignment placed an increased requirement on Society management for the establishment and initiation of an ASQC Standards program, which would assure an acceptable organization with high order professional and technical participation in the standards development arena. (See Figure 1.)

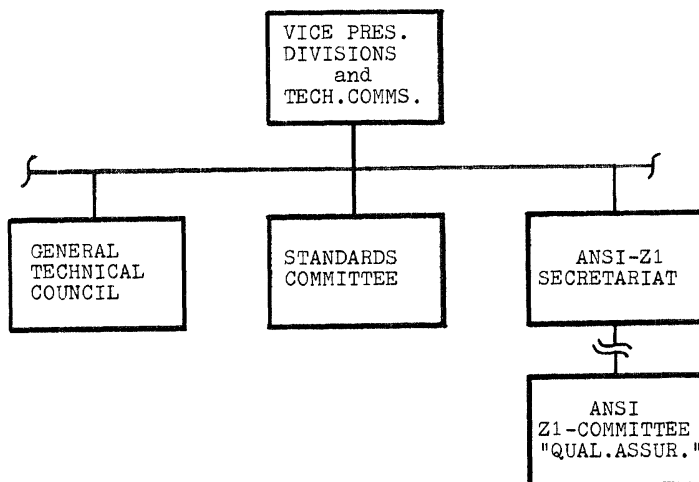


FIGURE 1.
ASQC STANDARDS OPERATIONS

A redefinition of the ASQC Standards Committee was undertaken with the following requirements in mind:

- a) Well defined ASQC policies.
- b) An effective Standards Committee organization
- c) An organization involving all interested ASQC Divisions and Technical Committees
- d) Procedures which would assure the Society and its members of professional visibility in the development and release of both ASQC and American National Standards

In view of the above, the ASQC Standards Committee has been organized as shown in Figure 2.

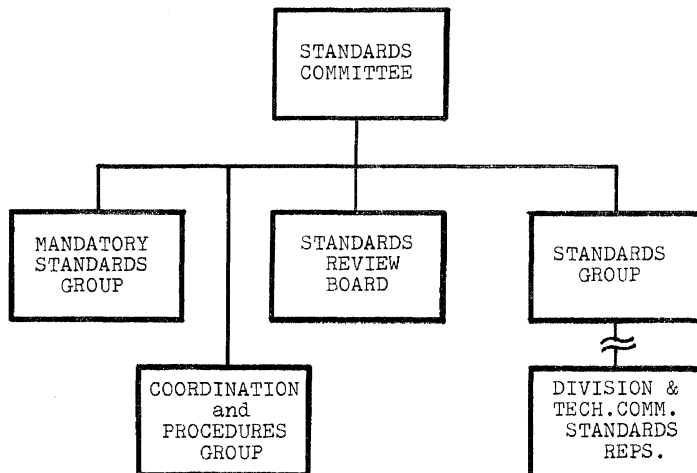


FIGURE 2.
ASQC STANDARDS ORGANIZATION

It should be noted that the Standards Committee has retained much of what was already in place and has added the functions of the Standards Review Board (SRB) and a formal representation of Divisions and Technical Committees by "Standards Representatives".

The Standards Committee, made up of members of the reporting groups, is responsible for management of the standards program in ASQC. Policies and Procedures, G-10, dated November 18, 1977, is the current management document which provides overall direction to the effort.

The Mandatory Standards Group is responsible for liaison with appropriate agencies of government that are producing mandatory standards that affect the quality and reliability discipline, and to provide a communicating link with technical units of the Society for appropriate technical advice and input to those agencies.

The Standards Review Board (SRB) is responsible for assuring that writing groups who have developed standards, have in fact, operated in accordance with designated procedures in establishing the required "National Consensus" when declaring either an ASQC Standard or an American National Standard.

The Coordination and Procedures Group, working in consonance with the ASQC technical staff and an associated Standards Document Control Center is responsible for assuring that appropriate procedures exist for both the overall operation of the Standards Program, as well as the control documentation required for the development, publication, and maintenance of the standards documents.

The Standards Group is responsible for assuring and maintaining the overall technical competence of the Society Program. It is also responsible for liaison and interface with the Division and Technical Committee Standards Representatives because of program dependence on these units as the source of technical expertise in the development and maintenance of standards documents.

As we noted previously, the involvement of the Division and Technical Committees in the Societies Standards Program is of paramount importance. The success of any standard document depends on a need, and this need can be best detected by professionals in the many industrial and service areas actively involved with the assurance sciences.

Members of the several division and technical committees are in a position to access such needs and, furthermore, transmit same into the ASQC Standards Program for evaluation and action. Therefore, it follows that strong standards initiating actions will originate with standards committees in these Divisions and Technical Committees.

The Society Standards Committee has a responsibility for assuring that we have a mechanism (both management and technical) which is capable of assisting in the prioritizing, and development, and in assuring that needed standards proposals which are entered into the system meet technical and procedural requirements and ultimately become available to users in the shortest possible time.

Division and Technical Committee Standards Representatives have a key role in assuring strong liaison between their respective D.T/C Standards Committees and the Society Standards Committee. This is a two way communications link since the overall concern is one of meeting an industrial or national need with precision and timeliness. As of January, 1978, we have 18 D.T/C Standards Representatives announced. (See Figure 3.)

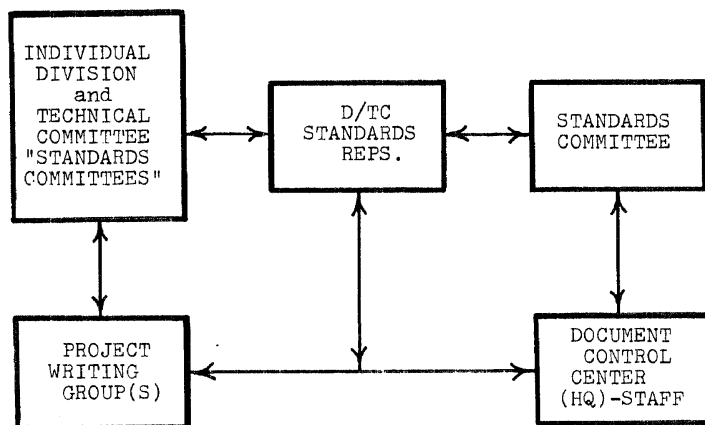


FIGURE 3.
ASQC-STANDARDS INTERFACE

It was recognized, early in the committee study, that in all probability there would be a significant increase in the number of persons involved in various phases of the standards program throughout ASQC. In order to assure that all participants receive the required operating guidance, the committee has published an "Operations Manual". The Coordination and Procedures Group is responsible for content and revision. The following is an outline of manual contents:

- 1.0 ASQC Standards Committee
Appropriate organization charts and administrative procedures for each of the Standards Groups and the Review Board.
- 2.0 Division and Technical Committee Representatives
Interface requirements for representatives within their respective division and technical committee standards operations, and in liaison with the Standards Committee.
- 3.0 Standards Development and Management Procedures
Seven operating procedures specific to the management of a standards project, as well as the technical requirements regarding document content and control.
- 4.0 ASQC/ANSI-Z1 Secretariat
Charges, rules and regulations for the operation of this committee.
- 5.0 Appendix "A"
Key ASQC management Policies and Procedures affecting the standards program. Also, the Standards Committee long range plan.
- 6.0 Appendix "B"
ANSI organization charts, and procedures. Also, the ANSI Style Manual outlining format requirements for an American National Standard.

What we have covered up to this point is a review and update of some of the past work done by our society in bringing the Standards Program in step with today's marketplace.

In the past, ASQC members and staff have been active participants along with members of such societies as ASTM, IEEE, SAE, ASME, UL and NEMA in the development of standards.

However, with accreditation we assume the responsibilities of initiation and authorship and including development, publication, and maintenance of standards document.

A review procedure, including detailed documentation of both the reviewers and writing group comments and/or action is a mandatory requirement as a part of pre-publication. Evidence of these data is under the control of both the ASQC Standards Review Board and the ANSI Board of Standards Review.

You have probably seen announcements in Quality Progress similar to this one which appeared in the December, 1977 issue. National consensus procedures require broad public exposure in order to meet ANSI requirements for comments during the development/draft stages of a voluntary standard. (See Figure 4.)

ANNOUNCEMENT

Revision to ASQC Standard A2-1071
(ANSI Standard Z1.6-1971)

"Symbols and Definitions for Acceptance Sampling
Involving Percent or Proportion Variant Units in
a Lot Batch"

IS NOW AVAILABLE FOR COMMENT

This revision is a major expansion in revised format of the second of three definitions standards published by ASQC. The revision contains 62 general sampling terms: 26 terms related to attribute sampling, 4 indices for acceptance sampling, and 32 terms related to variables sampling. The expansion covers the major sampling plan types for both attributes and variables techniques, including single, double, multiple, sequential, chain, skip-lot, continuous, and isolated lot. The standard is available by sending a pre-paid check or money order to:

The American Society for Quality Control
Attention: R. L. Griffith
161 W. Wisconsin Avenue
Milwaukee, Wisconsin 53203

Single copy price: \$4.00

COMMENT CLOSING DATE
FEBRUARY 15, 1978

FIGURE 4.
(Appeared in December 1977
issue of Quality Progress)

In view of the extraordinary coverage provided by 26 divisions and technical committees, ASQC members are in an excellent position to advance standardization in the assurance sciences as applied to a broad spectrum of processes, products, and services.

In the context of Industrial, National and International standardization, ASQC professionals who are interested in standards development and application will find broad opportunities for involvement in either the technical, or management aspects of standards operation. (See Figure 5.)

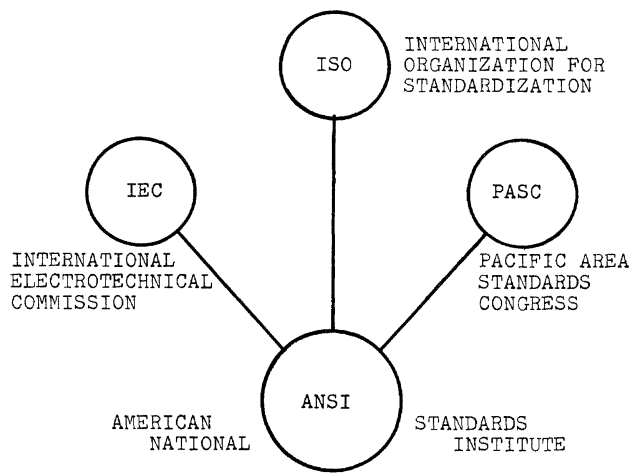


FIGURE 5.
ANSI-INTERNATIONAL INTERFACE

The ASQC Standards Program has the capability for assuring an effective involvement of members and staff in meeting ANSI requirements, with documents which support Industrial, National and International user needs.

LSC:342:00:000

ASQC/ANSI DEFINITIONS STANDARDS - A STATUS REPORT

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The ASQC Standards Committee was established in 1947 with the charge to "... study and select symbols, concepts, terms, procedures, and other matters which it feels the Society might standardize to advantage ...". The first standard it developed was A1-1951, "Definitions and Symbols for Control Charts". This was updated with slight modifications, primarily with respect to notation, in a 1969 revision which was adopted by ANSI in 1971 and issued as ASQC:A1-1971, ANSI:Z1.5-1971.

In 1957, a second definitions standard, A2-1957, "Definitions and Symbols for Acceptance Sampling by Attributes", was prepared. This was revised in 1962 as A2-1962 and again in 1971, primarily with respect to clarification and updating of comments associated with the original terms, and in 1971 it was adopted by ANSI and issued as ASQC:A2-1971, ANSI:Z1.6-1971.

A third definitions standard, A3-1964, "Glossary of General Terms Used in Quality Control" was issued in 1964. In 1971 this standard was enlarged to include some of the more general terms dealing with control charts and sampling, and some of the original terms were modified slightly. This revision was adopted by ANSI and issued as ASQC:A3-1971, ANSI:Z1.7-1971.

In early 1975, the ANSI Z1 Committee on Quality Assurance reviewed the overall needs for quality definitions standards. Almost concurrently, the ASQC Standards Committee decided that the time was appropriate for a major updating of all three of these ASQC standards. As a member of the Standards Committee, I was named chairman of a writing committee to accomplish this task. The Statistics Technical Committee was asked to recommend volunteers who would serve with me on this task group. For a little over two years now, the writing committee consisting of: T. W. Calvin, J. W. Foster, R. A. Freund, J. D. Hromi, J. S. Hunter, N. L. Johnson, J. V. Lavery, W. M. Mead, and H. M. Wadsworth has proceeded to extensively increase the number of terms defined, and to consolidate and unify the concepts and definitions included in the three original standards. The scopes of these standards were reevaluated in order that they would be consistent with the overall strategy proposed by the ANSI Z1 Committee.

It was decided that the scope of the A1 Standard should be expanded beyond the Shewhart \bar{X} and R and attribute charts that had been well treated in the original. Other more recent and widely used control chart techniques were to be included. For example, the Acceptance Control Chart, the Exponentially Weighted Moving Average Chart and the Cumulative Sum Chart have been included in the new revision. Furthermore, it was decided that this revision should attempt to show how these techniques relate to each other, and to indicate when each might be used most effectively.

The A2 Standard was to be enlarged to include variables sampling plans as well as those for attributes. In addition, we wanted to show the relationships among the different types of plans such as those for continuous processes with lots, continuous processes without lots, and isolated lots. We also wanted to contrast the different indexing systems such as AQL, LQL, AOQL and minimum cost to assist in the understanding of their selection.

Next, the A3 Standard was to be cleared of those terms that more properly belonged in the A1 and A2 Standards so that it could concentrate

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on a more extensive effort in the area of quality systems terminology.

Beyond these three standards, the ANSI Z1 Committee envisions documents on reliability, sampling in a general rather than acceptance sense, design of experiments, and an alphabetical glossary that does not involve the comparative comments of the detailed standards, but summarizes the full field of quality related terminology. Work is already under way on these.

Now let us look at the A1, A2, and A3 Standards in a little more detail. We are viewing the prime purpose of standards as a means of improving communications through consistency. A major source of difficulty in either the technical or non-technical fields is that a word or phrase is interpreted differently by various people, depending on their background and experience. George Bernard Shaw observed that "England and America are two countries separated by the same language". In our profession, as in others, we often use identical words, but they may mean quite different things. Sometimes this is a matter of general usage versus specialized technical usage, but quite often it represents an evolution in application.

Quality Control should be of interest to all kinds of manufacturing, processing, and service endeavors dependent on almost the entire gamut of the arts and sciences. With the large diversity of backgrounds involved, it is little wonder that our common language has been interpreted in so many ways. For this reason, we have chosen in these standards to make extensive use of explanatory and comparative comments and notes. This has lengthened the document, and perhaps made it a little less convenient to skim. However we felt it has added an important dimension to the usefulness of the standards. At the same time, we tried to resist the temptation to make these standards into textbooks or detailed "how to" explanations. The Statistics Technical Committee and other groups are working on that type of effort. There are a few technique oriented standards such as the B1, B2 and B3 series on Shewhart-type control chart construction and application, which now need updating, and there are plans under consideration for others of this nature. The function of the definitions standards, however, is to provide the common concepts for those who apply or explain the techniques and not to provide the detailed application examples.

One area that had to be tackled in dealing with control charts and acceptance sampling was the terminology associated with events that are being reported. Traditionally, the early textbooks, papers and applications dealt with a simplistic approach to language wherein words like "defect" or "defective" merely meant that something was different and was to be detected. Often these words were intended to indicate poor product, but many times the words were inappropriately used, although the true meaning was understood within the narrow confines of their specific application. For example, in recent CPSC hearings on sampling, concern was expressed about sampling plans with high AQL values described in terms of a relatively sizable percent of defective product. The meaning attached to "defect" by the groups raising the question was that the product would be unsafe or would not work in the hands of the consumer. In general, the sampling plans were intended to be used in terms of conformance to specifications which often were tightened in order to provide protection against such aspects. That is, the specifications were not given simply in terms of "fitness-for-use". Imprecise language was helping to create a significant barrier to understanding.

This subject has been widely discussed in the literature for many years, and in the February 1977 issue of *QUALITY PROGRESS* a report entitled "Saying What You Mean to Say" described the work being done by the writing committee in an attempt to clarify this confusion. Section 14 of the new ANSI/ASQC Standard A1-1978, "Definitions, Symbols, Formulas and Tables for Control Charts", includes the definitions of additional terms which, if used consistently, should help clarify this issue. This is not a word substitution game. "Defect" and "defective" are still part of the language, but are specific to "fitness-for-use" considerations. Conformance to specifications involves terms like "nonconforming units" or

"nonconformities". Most acceptance sampling really involves comparison with specification requirements, and while "fitness-for-use" must be considered in setting those specifications, it is not a direct relationship. Another term, "imperfection", has been introduced to recognize that something has deviated from some target without attaching judgment criteria as to whether specifications are satisfied or product meets the "fitness-for-use" criteria. This is important in control operations where trends give advance warning so that problems can be prevented.

Sections 1-3 of the ANSI/ASQC Standard A1-1978, "Definitions, Symbols, Formulas and Tables for Control Charts", deal with the general aspects of the Shewhart Control Charts, Acceptance Control Charts and Adaptive Control Charts. Sections 4-11 treat the specific variations in these charts, with section 12 defining general terms. Section 13 defines those terms related specifically to control charts for variables, including factors and formulas, and section 14 similarly treats those for attributes charts. Sections 15-17 deal with terms and formulas specifically related to Acceptance Control, Exponentially Weighted Moving Average and Cumulative Sum Charts, respectively.

The A2 Standard, "Terms, Symbols and Definitions for Acceptance Sampling Involving the Percent or Proportion of Variant Units in a Lot or Batch", is divided so that Section 1 covers general acceptance sampling terminology. Sections 2 and 3 are specifically related to attributes sampling. Section 4 deals with the types of indices. Sections 5 and 6 relate to variables sampling.

The A3 Standard, "Quality Systems Terminology", defines such basic terms as quality and reliability, quality systems, quality programs, quality assurance, quality control, quality engineering, reliability engineering, quality audits and related terms. As in the other two standards, comments and notes are used extensively to describe relationships among these functions.

In summary, we have made considerable progress in describing and defining some of the fundamental terminology and concepts for the quality profession. Work is continuing now on the additional important areas that fit into the overall goals of the ANSI Z1 Committee on Quality Assurance.

LCS: 010:00:000

STATUS REPORT OF Z1.15 SYSTEMS STANDARD

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In 1973, the American National Standards Institute asked ASQC to assume the Secretariat of a new Quality Assurance Committee. One reason for the need of such a committee was the fact that many new product standards were being written containing Quality Assurance provisions. Standards writers recognize that not only must a product standard specify criteria to be met by the end product, but the means of accomplishing this in mass production must be considered. When the ANSI Z-1 Quality Assurance Committee was formed, it was understood that there was an urgent need to develop a generic Quality Systems Standard that would be usable either directly, in modified form, or as a reference, for inclusion in product standards.

At about the same time five years ago, a group of Quality Assurance Managers working in consumer products industries were already engaged in an effort to prepare a Quality Assurance Systems document that would be applicable to consumer products. Our concern at that time was that the existing quality systems documents had been developed for use in defense, aerospace and large commercial installations, but were not directly applicable to mass-produced consumer products, and applicable or not, were in fact seldom used in consumer product lines. We were looking towards the development of a quality systems standard that would be used in industries in which we worked. Shortly the Consumer Products Committee found itself aiding in systems standard development, and taking part in the Z-1 Committee effort.

Two years ago, at the 30th annual Technical Conference of ASQC in Toronto, Canada, we discussed the status of our work in the preparation of the generic Quality Systems Standard. As reference, some of the material presented at that time is included as background to today's presentation.

Rather than first searching out the many product standards which include various Quality Assurance provisions, the ANSI Quality Assurance Sub-Committee that addressed the problem of developing a generic Quality Systems Standard took the existing umbrella standards which came to its attention, and outlined them to establish their scope and content. Table I lists an initial group of such standards, British and Canadian documents, and various other works containing different degrees of technical depth, and using various approaches to describe Quality Assurance systems. Each of the first group of standards were outlined by the Committee to identify the subject areas covered. Tables II and III are outlines of two of these standards. Next, a matrix was prepared to compare the contents of the standards to each other. While incomplete, and containing some inaccuracies, the matrix does demonstrate that not only does the content of the various documents vary considerably, as would be expected, but no one document seems to define all significant areas of a Quality Assurance system.

The Committee task was to construct a new outline, covering all elements of Quality Assurance systems which seemed significant. This was done by first listing all of the outlined subjects on 3 x 5 cards, and sorting until a logical and workable order was achieved. This initial sorting demanded certain working decisions which had an influence on the end result. For example, while elements of a quality system such as receiving inspection, in-process inspection, or final inspection are separately definable, the subject of the use of statistical methodology might be included under each of the various inspection elements, or might be presented in a single section and cross-referenced. This latter course was chosen, somewhat arbitrarily, in order to avoid repetition and to reduce the size of the final document.

When a "complete" outline was developed, portions of the outline were assigned to writing teams for "fleshing out". To do this, since the content of the original input document had been cross-referenced, copies of each of the sections of the input documents were given to each of the section writing teams. While

they worked with the original outline, they had access to the content of the other documents and were encouraged to be guided by these documents.

During the working sessions of Committee efforts to develop the document, questions came up as to the objectives as well as the mechanics of accomplishing the writing of a usable generic document. It was soon recognized that, because of its scope, not all products or industries would use all of the elements of the generic Standard. Thus, as a generic document, the Standard would be used as a basis for developing specific documents for individual product lines and industries.

In working with the generic guidelines, the user must realize that the degree of control necessary for a specific product or production situation will vary, and should be reflected in the Standard, as modified. The thoroughness required for Nuclear power Standards is inappropriate for shoe manufacture. Quality system requirements related to user safety for television sets place demands far beyond those required for bedspread manufacture, even though the basic principles upon which the control systems are based are remarkably similar.

A perishable food item may actually require all elements of a Quality Assurance system, but not all details of each element will apply. The Standard discusses installation, service and use in the section of Field Performance. While acceptable performance to the user is at least as essential for a food product as with any other product, food does not require assembly instructions or spare parts. Consequently, items such as these must be reviewed for appropriateness to the product, and rewritten so that they will directly apply. In contrast, a complex consumer product, such as an electronic device, might well require application of all elements (chapters) of the Standard, from planning and design assurance, through field performance and corrective action. Indeed, portions of the Appendix (that are technically not a part of the Standard) might also be included as a part of the Standard for an electronic item, because of their relative importance.

The question was posed as to why such a Standard is needed, when so many other documents are available? The wisdom of our answer will be proven out at a later date, when it is established whether the generic Standard does serve a purpose to industry. As noted in the matrix, possible shortcomings of most of the existing quality systems documents were in one or two areas. Some do not provide for adequate system pre-planning; a second shortcoming was often the lack of inclusion of follow-through of the product to the user, and the feedback of usage information back to the manufacturer. And even where these were included, they often were not covered in proportion to their importance in today's industrial climate.

Within this past year, after considerable deliberation by Committee members, the name of the document was changed to "Generic Guidelines for Quality Systems." This change was made when it became evident that without it the use of the document could be misunderstood. This change strikes at the heart of the intent and purpose of the Standard. The Foreword, Statement of Scope and Application sections of the document clearly state the intended usage. However, without the word "Guidelines" in the title, there remained the very real danger that the use of the Standard, in toto, and without modification, would be dictated for use in cases where only a portion of the document should actually be put into use, or where modifications were essential.

The end result of the work of developing the Generic Quality Systems Guidelines is a broad document that we believe includes all significant elements of Quality Assurance from design concept through end usage, feedback and extended use in service. It is intended that all are in logical balance. The Guideline is a framework against which individual product guidelines can be developed following the same structure or format. It provides an expression of the basic elements of Quality Assurance that can be applied in essentially all areas of manufacture of commercial, industrial and consumer products. It is hoped that its existence will now aid major areas of American and world industry in understanding the basics of Quality Assurance. A list of Committee members is attached. However, it is impossible to list all who have made valuable contribution to the Standard.

Briefly, here are the basic sections of the document:

1. Foreword and Scope. The abstract of the document states "Generic Guidelines for Quality Systems covers and briefly describes the significant elements that should be considered in the quality system of a manufactured product. This embraces quality policy, design assurance, quality control at various stages of production, field performance and product liability. The Standard is intended to provide Generic guidelines for a product quality system. As such it is not directly applicable to individual products or industries, but must be tailored to the specific case, making use of each element that is applicable."
2. Application. This section stresses the advisory nature of the guidelines, and the need for continually updating a quality system so that it will not stagnate.
3. Definitions of Terms Used in Quality Systems. The list of terms defined in the Standard is brief, since longer lists of quality terminology are available in existing ANSI/ASQC Standards A1, A2 and A3 and elsewhere. Definitions in the Guidelines document are limited to basic concept terms such as "Quality of Design", "Quality Systems", "Quality Control" and "Quality Assurance."
4. Policy Planning and Administration. This section calls for a written Quality Policy, including objectives and an organized approach for carrying them out.
5. Design Assurance provides for design validation and re-qualification, plus design change (Configuration) control.
6. Control of Purchased Materials includes:
 - Review of supplier quality capability
 - Supplier quality information
 - Quality Control or surveillance at source
 - Receiving inspection, and
 - Identification of purchased materials
7. Production Quality Control provides for:
 - Planning and controlling the process
 - Completed item inspection
 - Handling, storage and shipping
 - Product identification
 - Development and use of quality information
8. User Contact and Field Performance includes:
 - Statements of product objectives
 - Review of advertising information
 - Use of sales and service organization quality information
 - Control of installation, service and use, and
 - User/consumer feedback
9. Corrective Action includes:
 - Procedures for detecting and reporting problems
 - Evaluating and follow-through to correction

The Appendix includes:

- Sampling and Other Statistical Tools
 - Employee Selection and Motivation
 - Measurement Control of the Inspection Process
 - Product Liability and User Safety
 - Economics of Quality Control
-

As the Standard is actually put into use, the ANSI Z-1 writing group has several alternative new writing tasks to consider. It intends to aid in the application of the Standard to specific industries or products. It is considering the writing of a "How to do it" supplement, that will expand upon each of the sections. (Actually, much of this is available as a result of Committee work already completed.) It also has been suggested that a more concise version of the Standard be prepared for wide distribution in industries where Quality Control techniques are less well understood. Any or all of these various efforts may be embarked upon. But most important at this time is the effective application of the Z 1.15 Standard in places where it is needed and can be effectively used. To do that requires careful, professional application of the Standard by those who understand the principles upon which it is based. Only then can it become a worthwhile contribution to the Quality Control profession.

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TABLE I

SELECTED BOOKLETS AND PUBLICATIONS
DESCRIBING QUALITY ASSURANCE PROGRAMS

U. S. Organizations - General

Specification of General Requirements for Quality Program	ASQC Standard C-1 ANSI Std. Z1.8 - 1971
Procurement Quality Control A Handbook of Recommended Practices	ASQC Vendor - Vendee Technical Committee - 1973
Practice for Certification by Producer or Supplier	ANSI Z-34.2 - 1969
Quality Program Requirements	MIL-Q-9858A 16 December 1963
Evaluation of a Contractor's Quality Program	Handbook H-50 - 31 October 1960
Inspection System Requirements	MIL-I-45208A - 16 December 1963
Evaluation of a Contractor's Inspection System	Handbook H-51 - 3 January 1967
Supplier Quality Assurance Program Requirements	MIL-STD-1535 (USAF) - 1 December 1972
Safety in the Marketplace (Orange Cover)	National Business Council for Consumer Affairs (April 1973)
Product Performance and Servicing (Green Cover)	National Business Council for Consumer Affairs - September 1973
A Tested System for Achieving Quality Control	SBA Technical Aids No. 91 - January 1969
A proven Method of Quality Control	Research Institute Recommendations 9-9-66
Product Safety	Employers Insurance of Wausau Symposium - June 1968

CANADIAN/BRITISH BOOKLETS

Quality Assurance	Canadian Standards Association April 1973
A Guide to Quality Assurance	BS 4891:1972 - British Standards Institute
Quality Assurance Requirements for Industry	British Standards Institute 73/85038 - May 1973

SPECIFIC INDUSTRIES OR PRODUCTS

Quality Assurance-Criteria for Nuclear Power Plants	Appendix B to 10CFR50 - June 1970
Requirements for Electronic Component Parts Manufacturers	(1) Inspection System Requirements (2) Quality Program Requirements

TABLE II SPECIFICATION OF GENERAL REQUIREMENTS FOR A QUALITY PROGRAM
ASQC STANDARD C1

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <u>Definition of Terms</u> <ol style="list-style-type: none"> 1.1 Quality Program 1.2 Contractor 1.3 Buyer 1.4 Inspection 2. <u>Scope</u> <ol style="list-style-type: none"> 2.1 Applicability 2.2 General Expense 3. <u>Requirements</u> <ol style="list-style-type: none"> 3.1 <u>Quality Management</u> <ol style="list-style-type: none"> 3.1.1 General 3.1.2 Organization 3.1.3 Procedures 3.2 <u>Design Information</u> <ol style="list-style-type: none"> 3.2.1 General 3.2.2 Change Control 3.3 <u>Procurement</u> <ol style="list-style-type: none"> 3.3.1 General 3.3.2 Source Information 3.3.3 Fabricated Material 3.3.4 Raw Materials | <ol style="list-style-type: none"> 3. <u>Continued</u> <ol style="list-style-type: none"> 3.4 <u>Material Control</u> 3.5 <u>Manufacturers</u> <ol style="list-style-type: none"> 3.5.1 General 3.5.2 Process Control 3.5.3 Special Processes 3.6 <u>Acceptance</u> <ol style="list-style-type: none"> 3.6.1 General 3.6.2 Sampling Inspection 3.6.3 Nonconforming Material 3.7 <u>Measuring Instruments</u> 3.8 <u>Quality Information</u> <ol style="list-style-type: none"> 3.8.1 General 3.8.2 Quality Control Records 3.8.3 Corrective Action 4. <u>Quality Program Audits</u> |
|---|---|

TABLE III QUALITY PROGRAM REQUIREMENTS MIL-Q-9858A

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <u>Scope</u> <ol style="list-style-type: none"> 1.1 Applicability 1.2 Contractual Intent 1.3 Summary 1.4 Relation to Other Contract Requirements 1.5 Relation to MIL-45208 2. <u>Superseding, Supplementation & Ordering</u> <ol style="list-style-type: none"> 2.1 Applicable Documents 2.2 Amendments and Revisions 2.3 Ordering Government Documents 3. <u>Quality Program Management</u> <ol style="list-style-type: none"> 3.1 Organization 3.2 Initial Quality Planning 3.3 Work Instructions 3.4 Records 3.5 Correction Action 3.6 Cost Related to Quality 4. <u>Facilities and Standards</u> <ol style="list-style-type: none"> 4.1 Drawings, Documentation and Changes 4.2 Measuring and Testing Equipment 4.3 Production Tooling Used as Media for Inspection 4.4 Use of Contractor's Inspection Equipment 4.5 Advanced Metrology Requirements 5. <u>Control of Purchases</u> <ol style="list-style-type: none"> 5.1 Responsibility 5.2 Purchasing Data | <ol style="list-style-type: none"> 6. <u>Manufacturing Control</u> <ol style="list-style-type: none"> 6.1 Materials and Materials Control 6.2 Production Processing and Fabrication 6.3 Completed Item Inspection and Testing 6.4 Handling, Storage and Delivery 6.5 Nonconforming Material 6.6 Statistical Quality Control and Analysis 6.7 Indication of Inspection Status 7. <u>Coordinated Government/Contractor Actions</u> <ol style="list-style-type: none"> 7.1 Government Inspection at sub-contractor or Vendor facilities 7.2 Government Property <ol style="list-style-type: none"> 7.2.1 Government-furnished Material 7.2.2 Damaged Government-furnished Material 7.2.3 Bailed Property 8. <u>Notes</u> <ol style="list-style-type: none"> 8.1 Intended Use 8.2 Exemptions 8.3 Order Data |
|--|---|

SYSTEM RELIABILITY ANALYSIS: A TUTORIAL

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INTRODUCTION

This paper deals with the logical formulation of a system for purposes of reliability analyses and both exact and approximate methods of calculating the system reliability. The first part deals with the logical concepts, and the second part with probability calculations.

The logical formulation in Part 1 starts from first principles. The universal set U of system states is a "Boolean algebra". The "power set" \mathcal{P} is the set of subsets of U . The subset of system success states or "paths" is a "lattice" within U , also an element of \mathcal{P} , represented by a Boolean polynomial. The terms of the polynomial are monomials which give the indicators for the "sublattices" or "complete subsets" of U within the lattice of paths. The optimal representation of this lattice polynomial is in the minimalized form; the terms of the minimalized lattice of paths are called the "minimal paths". Similarly, the subset of system failure states or "cuts" is a lattice polynomial whose terms are sublattices within the lattice of cuts; the terms of the minimalized lattice polynomial are the "minimal cuts". Logically consistent systems (also known as "coherent structures") have certain properties with respect to the partial ordering of paths and cuts. The concepts of Boolean logic, minimalization, etc., apply to systems that do not have the "consistency" property, as well as to those that do have it.

The second part of this paper deals with ways of using a minimalized lattice polynomial to derive a numerical-valued probability function from which to calculate the system reliability: also computer software, error bounds and approximations. The reliability is the probability that the actual state of the system is an element of the lattice of paths. The exact probability is derived from the minimalized lattice polynomial of paths by the method of inclusion-exclusion, also known as Poincare's Theorem. Dually the probability of failure, or system unreliability, is derived from the minimalized lattice of cuts. Modularization and/or inversion can be helpful in keeping the probability function reasonably small in size. Computer software is available both to generate the probability polynomial and to calculate either the reliability or unreliability. Approximations can be used based upon simplifying assumptions which delete low probability terms from the function. Conservative error bounds are obtainable for some models. The approximation techniques include serializing methods ("single-point failures" and "parts count"), very large system approximations for fault-tree applications and the Esary-Proschan bounds.

DISCUSSION

System reliability analysis is closely related to Boolean logic. From George Boole's classic 1854 book, The Laws of Thought [6], it can be seen that the kinds of problems Boole was trying to solve

... to make that method itself the basis of a general method for the application of a general method for the application of the mathematical doctrine of Probabilities ... [6, p. 1]

... it is always possible ... to express the event whose probability is sought as a logical function of the events whose probabilities are given ... [6, p. 15]

is essentially the same problem that a system reliability analyst tries to solve. In this paper we interpret the objective to be that of logically symbolizing the success or failure of a system as a function of success or failure for various combinations of its components, and evaluating the probability of success, that is, the system reliability, as a function of the component reliabilities.

Boole made some errors. His explanation of "inversion" involved a clumsy use of series expansions and divisions by logical zero, in contrast to the more elegant de Morgan's theorems. Also he did not exhibit a deep understanding of "duality". Subsequent work by others based on Boole's foundations, led to many significant developments in mathematics, symbolic logic and philosophy, including set theory, particularly lattice theory and the theory of partially ordered sets, Boolean algebra and minimization by Quine [24, 25, 26]. The contributions of Boolean logic to applied disciplines such as computer science and electrical engineering, particularly through the pioneering work of Shannon [30], are well known and recognized.

Logically based system reliability analysis appears to have been initiated by von Neumann in connection with his search for ways of explaining how large digital computers having many thousands of unreliable components such as vacuum tubes could operate reliably. In a paper published in 1956 based on lectures given in 1952 at Cal Tech, von Neumann [35] showed that by the use of redundancy, it is possible to build and maintain a complex system having a greater reliability than any of its components.

Moore and Shannon [20] used essentially parallel-series circuits consisting exclusively of idealized identical relays all with identical reliabilities to develop functions relating the reliability of a system R to that of the components. Bounds on this relationship were developed showing at what point R could be greater than the components. Mine [19] generalized this work further by introducing Boolean and set-theoretic notation, and employed linear graph theory to find the functional relationship between system and component reliability. He also developed bounds and conditions under which arbitrarily high R could be obtained.

Birnbaum, Esary and Saunders [5] extended the Moore-Shannon approach to the general class of "coherent" systems that have certain logical consistency properties. That paper introduced terminology which has been widely used, such as "minimal paths", "minimal cuts" and "essential (relevant) components". Esary and Proschan [10, 11] obtained approximations for the reliability of coherent systems, including upper bounds based on the minimal paths and lower bounds based on the minimal cuts. The theory of coherent systems based on this general approach is discussed by Barlow and Proschan [3, pp. 1-51], and a review of the literature, with special reference to the contributions of Z. W. Birnbaum and his students and colleagues, is given by Saunders [28].

The research reported upon in the body of this paper deals primarily with generalized approaches that apply not only for a complex system of any configuration, but also if every component is different. Several large scale computer programs of this type were prepared in the early 1960's in connection with the U.S. space program. Some of these programs employed Monte Carlo. As a general rule, very little documentation is available as to what theory was employed or what was done.

A FORTRAN software package with the acronym SCOPE (System for Computing Operational Probability Equations) was developed about 1965 at the Rockwell International Corporation. SCOPE provides an exact system reliability function of the component reliabilities for a complex system of any configuration but of limited size, based on either the minimal paths or else the minimal cuts. This function is derived by the method of inclusion-exclusion, also known as Poincare's Theorem. To obtain the system value, simply substitute the component values into this function. The SCOPE software is available through NASA [23], and the mathematical theory is given in [15], including some comparisons to the Esary-Proschan bounds.

An improved version of SCOPE was prepared in 1972 by Burris [7] at Oklahoma State University with the acronym MAPS (Method for the Analysis of the Probabilities of Systems). Instead of FORTRAN, it is programmed in PL/I, which is better adapted to binary-digit manipulation. It also incorporates a modularity feature so that the system can optionally be processed as a complex configuration of independent modules, each module consisting of a complex configuration of independently failing elements. Consequently there is simultaneously both an increase in capacity and a saving in computer time, over the requirements of the parent SCOPE program.

A further extension of MAPS is SPARCS (Simulation Program for Assessing the Reliabilities of Complex Systems) programmed by Cooley [8] at Oklahoma State University under Air Force Contract F33615-74-C-4072. This uses Monte Carlo combined with Bayesian techniques to assess (provide a schedule of confidence levels for all values of R between 0 and 1) both R and the MTBF (mean time between failures) of a complex system of any configuration consisting exclusively of pass/fail and/or time-to-failure components, or any mixture of these, from failure-history data. Both MAPS and SPARCS are described in [16]. A more efficient version of SPARCS, called SPARCS-II has been

A related and parallel effort to SCOPF and its daughter programs (or SPARCS and its parents) is the development of the fault-tree methodology. Initially designed for aerospace applications at Bell Labs [4] in 1961, and subsequently also at Boeing Airplane Company, as an aid to engineers in analyzing sequences of events leading to system failure, it has recently been used extensively for reactor safety studies by the Atomic Energy Commission and its successor, the Nuclear Regulatory Commission. A recent but historic document reporting the results of extensive applications of the methodology on the "Rasmussen Report WASH-1400" [31], particularly Appendix II, "Fault-Trees". Descriptions of the methodology are to be found in Mearns [18], Haasl [12], Eagle [9], Schroder [29], Barlow and Lambert [3], Vesely [33, 34, 35], and Barlow and Proschan [3, pp. 264-266].

A fault tree is a Boolean-equivalent diagrammatic representation of all the ways of failing a complex system through combinations of failures and repairs of one or more components. It is derived from block diagrams, schematics, and/or blueprints, and logical analysis of the interrelationships of the elements. "Minimal cut sets" are obtained from the tree. By substituting the component values, an estimate of R, the system availability or the failure rate are obtained. A rather substantial library of fault-tree methodology computer programs is available, including programs which build the trees, find the cut sets, or perform numerical evaluations. Vesely made some major contributions with the development of the PREP and KITT codes [32, 33]. Salem, Apostolakis and Okrent [27, pp. 34-45] and Worrell and Burdick [36] give reviews of the available software.

In general, the fault-tree methodology incorporates the same Boolean and probabilistic theory that SPARCS and its parent programs do. However, because the methodology is generally applied to large systems having only low failure-rate components, various types of "rare event approximations" are employed, to save computer time. These include both Monte Carlo and deterministic selections of components and cut sets according to importance, deleting higher order intersection terms in the probability equation, and basing calculations on failure rates rather than probabilities. "Importance" measures are discussed by Nagel [21], Nagel and Schroder [22], Lambert [13] and Mazumdar [17] in [1], and Barlow and Proschan [3, pp. 26-29].

This article is a review of the state of the art of evaluating R for a complex system as a function of the reliabilities or failure rates of the elements. It develops the common Boolean theoretical structure which underlies all the different methodologies, and shows some of the similarities of and the differences between exact methods and approximations. There are two parts: Part 1, on "Logical Formulation" and Part 2 on "Probability Calculations".

Part 1 of the paper gives the logical formulation, starting from set-theoretic first principles, from the viewpoint of lattice theory. We describe the universal set U of system states and power set \mathcal{Q} of lattices or events which are subsets of U . Events such as system success or system failure are collections of success states, called "paths", or else failure states, called "cuts", described by lattice Boolean polynomials. The terms of the minimalized form of the "success" polynomial are the "minimal paths" and for the "failure" polynomial the "minimal cuts" where each term denotes a sublattice.

Part 2 describes how to calculate the system reliability. First a probability function, a numerical-valued function of the component probabilities, is derived from the lattice polynomial by the method of inclusion-exclusion. Then the component probabilities are substituted into this function. Part 2 discusses exact methods, error bounds, approximations, serializing methods and the fault-tree methodology.

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WHAT ARE QUALITY COSTS

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ABSTRACT

In the area of quality control, the most efficient route to meet industries' challenges of improving product quality and lowering quality costs is to make the product (or provide the service) correctly the first time. Departures from this route incur unnecessary expense.

With the proper tools for measuring quality cost data and a program for presenting quality cost information, trends can be established as guides for management in pursuing these challenges.

The purpose of this presentation is to introduce a system to organize certain quality related costs enabling management to effectively measure and optimize quality costs as well as product quality.

The system is described in detail in the ASQC publication, "Quality Costs - What and How", prepared by the Quality Cost Technical Committee, ASQC.

LCS 353:30:000

THE PHILOSOPHY AND USEFULNESS OF QUALITY COSTS

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DEVELOPMENT OF THE GUIDE

The "Guide for Reducing Quality Costs" was developed following a realization by members of the ASQC Quality Cost Committee that very little guidance existed on what to do with quality costs once they were defined, categorized and collected as described in "Quality Costs" - What and How". Several of the members of the committee had experience in setting up and implementing successful quality cost reduction programs. Several of the companies represented had internal guides and literature on the subject. It was felt that quality management and general management would benefit from a how-to book dealing with what uses could be made of quality costs and the structure of programs to reduce the costs. The "Guide for Reducing Quality Costs" is an attempt to tell management:

- . How to analyze their quality programs using quality costs.
- . How to structure programs for reducing costs.
- . How to find areas needing improvement.
- . How to reduce failure costs.
- . How to reduce appraisal costs.
- . How to prevent quality costs.
- . How to measure improvement.

The guide represents many hours of work on the part of those people listed in the front of the guide. My presentation in this session will closely follow the content of the first five sections of the guide:

1. Purpose and Quality Definitions
2. The Quality Cost Improvement Philosophy
3. Usefulness of Quality Costs
4. The Quality System
5. Finding the Problem Areas

Following sections of the paper summarize the content of each section of the guide, but do not repeat the content or contain detailed explanations. The reader is referred to the guide for such detail.

PURPOSE

The purpose of the publication is to provide guidance to general management and quality program management to enable them to structure and manage programs for Quality Cost Reduction. The guide provides the procedures for taking total quality costs and using them for identifying problem areas and for reducing these costs. Quality costs covered include those in the design, manu-

facture, inspection, test, and product service phases. Improvement programs must encompass all phases of product life, from design through use by the customer.

THE QUALITY COST IMPROVEMENT PHILOSOPHY

The guide is about a quality program not confined to the control of quality in the manufacturing stage. Most people recognize that product quality is determined by many factors outside this stage, but many quality programs do not concern themselves with these factors. In some cases, quality program efforts have been attempts at not allowing things to get any worse (control) instead of striving to get better (improvement). As a result, things have gotten worse in many places, simply because controls are not 100% effective and can never be. Improving quality is much like improving product costs. It is everybody's job and everybody is for the idea, but, until there is a management commitment to improve and a formal program for forcing improvement, it just doesn't happen.

The guide describes what each function must do to satisfy the customer's needs and reduce your quality costs. Also described are ways to prevent the production of defectives through involvement of people in Marketing, Design, Purchasing, Accounting, Manufacturing, and Quality Assurance. It describes ways to find problems and correct their causes. It tells you how to use the costs associated with quality and how to reduce those costs.

Quality improvement results in cost improvement. Designing and building a product right the first time always costs less. Solving problems with existing products by finding their causes and eliminating them results in measurable savings. To cash in on these savings requires that the quality performance of the past be improved and the guide describes ways to do that.

The chart in the guide shows how quality cost analysis bridges the gap between the elements of a prevention oriented quality program and the means used by general management to measure performance - the profit and loss statement.

USEFULNESS OF QUALITY COSTS

Quality costs are useful for strategic planning and programing quality improvement.

STRATEGIC PLANNING

Strategic quality program planning is vital to the continuing profitability of many segments of American Industry. The pressures for safer, cleaner, and more reliable products are becoming stronger each year. We must find ways to meet these increasing demands and still remain competitive. The key to doing this is to improve quality using the methods described in this guide, and reduce costs as a result.

To improve quality and reduce quality costs there has to be a trigger for making changes in the status quo. The firm's Strategic Plan is an ideal device to force changes; and the inclusion of quality and quality cost improvement plans in the overall strategic plan is recommended. This gives the quality and quality cost situation the management visibility too often lacking. Because quality and quality cost improvements are set forth as business objectives (along with the more conventional business objectives) against which management performance is evaluated, there is effective motivation for action.

Relationship Between Quality Costs and Strategic Planning

Quality costs for a profit center are made up of costs incurred in several activities. The chart in the guide shows the buildup of costs from all functional departments into an overall quality cost analysis for the entire profit center.

Quality costs are incurred by all major functions in an organization, so problem areas can exist anywhere. Careful analysis must be done to find the most costly problems and programs must be developed to attack them. Many times a strategic program is needed. When this need exists, a strategic quality program should be developed using inputs from all functions and it should become a part of the profit center's overall strategic program.

The Planning Process

Strategic planning should be done in a step by step process. The basis steps are:

- . Review past performance and present position
- . Appraise the environment
- . Set objectives
- . Select a strategy
- . Implement the strategic program
- . Report and evaluate the plan

The final step in the cycle provides needed inputs for the first step so planning becomes a continuous process. Following are general considerations for accomplishing each step in the cycle.

Review Past Performance and Present Position - A thorough review provides a realistic assessment of past performance, current conditions, and future potential.

Appraise the Environment - There are numerous environmental factors which may significantly interact with the quality programs. Typical examples are:

- . The activities of other departments.
- . Changes in customer demands.
- . New safety and liability regulations.
- . Actions of competitors.

Set Objectives - From the knowledge and understanding achieved in the status review and the environmental information, the strengths and weaknesses of the quality program should be known. So, specific objectives with target completion dates can be established.

Select a Strategy - Once clear objectives have been established, a definite strategy should be formulated and clearly stated.

Implement the Strategic Program - Planning for the implementation of the strategy is the most important step of the planning process. All prior effort leads up to the implementation or action step. There are many cases of "that was a sound strategy but nothing happened as a result". This situation is due to a failure to follow up the strategy with appropriate action programs.

Report and Evaluate the Plan - The final step in the planning cycle is one of integrating the strategic quality plan into the total strategic plan and evaluating the costs and benefits of the plan.

Through better planning, quality performance can be improved. Continued achievement of good performance can identify the quality program as a key contributor to the success and assure that Quality will play an enlarged role in future plans and activities.

PROGRAMMING IMPROVEMENT

The Strategic Quality Plan describes a management commitment to quality and quality cost improvement. The quality cost data indicate the areas that are candidates for improvement. When the highest cost areas are analyzed in greater detail many improvement projects become apparent. For example, high warranty costs are a trigger to rank customer failure problems for detailed investigation, with the aim of looking into product design, process control, or inspection planning for the cures to the highest cost problems. Regardless of what the high quality cost category may be, the mere act of identifying it should lead to actions to reduce it.

To effectively program quality improvement efforts, it is necessary to:

- . Recognize and organize quality related costs to gain knowledge of magnitude, contributing elements and trends.
- . Analyze quality performance, identify major problem areas and measure product line and/or manufacturing section performance.
- . Implement effective corrective action and cost improvement programs.
- . Evaluate effect of action to assure intended results.
- . Program activities for maximum dollar pay off and maximum effective manpower utilization.
- . Budget quality work to meet objectives.

THE QUALITY SYSTEM

Perhaps the most important result of the collection, analysis, and use of quality costs is the exposure given to the total quality system as it really exists in the organization. The collection of costs forces definition of all activities contributing to the quality of the product. Analysis of quality cost data forces evaluation of the effectiveness of the contribution of each activity, the relationships among the many activities, and the all-important communications links that tie activities together.

Each organization will define its quality system differently, but the overriding requirement is that whatever definition is used must be comprehensive. That is, it must include all efforts that affect product quality, wherever the efforts are accomplished in the organization.

If there is a weakness in the quality system, it is usually a deficiency in the integration of the elements and their sub-elements into a working whole. Almost every manager can look at his system elements and convince himself that his organization has something going in each area - perhaps he even has a shelf full of procedures manuals to prove it. However, much of what is actually going on in the quality system might be superficial, or might not be well integrated into the operations and traditions of the total organization.

The concept of quality costs is a potent tool for management precisely because it can be used to force the integration of all the separate quality activities into the mainstream of the product cycle; that is, into a total quality system. It forces the entire organization to examine each cost element (and each quality-related activity) in the context of the total quality cost (and total quality system).

FINDING THE PROBLEM AREAS

When quality costs are displayed to managers who have not been exposed to the concept, the initial question is likely to be "how much should they be?" or "how does this compare with other organizations or products?" Unfortunately, it is not practical to establish any meaningful absolute standards for such cost comparisons. A quality cost system should be "tailored" to a particular company's needs, so as to perceive trends of significance and furnish objective evidence for management decisions as to where assurance efforts should be placed for optimum return. The search for "industry guidelines" or other standards of comparison, while natural, is quite dangerous, since it leads to quality costs emphasis for "score-carding" instead of utilization as a management tool for improving the status-quo.

The futility of establishing meaningful absolute quality cost guidelines is more apparent if you just consider:

1. Inherent Key variations in how companies interpret and capture quality cost data;
2. Critical differences in product complexity, process methods and stability, production volume, market characteristics, management needs and objectives, customer reactions, etc;
3. The awkwardness or inappropriateness for many companies of the most prevalent form of quality cost measure (% of net sales billed), considering effect of time differences between time of sales billing and incurrence of actual quality costs.

This last factor is particularly important for periods involving an expanding or contracting product volume or mix, unstable market pricing, shifting sales/leasing revenue ratios, or changing competitive performance criteria. Accordingly, it is much more productive to abandon efforts to compare your quality cost measurements with other companies, in favor of meaningful analysis of the problem areas contributing most significantly to your quality costs, so that suitable corrective actions can be initiated.

Analysis techniques for quality costs are as varied as those used for any other quality problems in industry. They range from simple charting techniques to complicated mathematical models of the program. The most common techniques are:

1. Trend Analysis
2. Pareto Analysis
 - A. By Element Group
 - B. By Department
 - C. By Product
 - D. Other Groupings

Trend Analysis is simply comparing present cost levels to past levels. It is suggested that costs be collected for at least one year before attempting to draw conclusions or plan action programs. The data from this one year (minimum) period should be plotted in several ways.

The Pareto Analysis technique involves listing the factors that contribute to the problem and ranking them according to the magnitude of their contribution. In most situations, a relatively small number of causes or sources will contribute a relatively large percentage of the total costs. To produce the greatest improvement, effort should be spent on reducing costs coming from the largest contributors.

LCS 353:10:000

REDUCING APPRAISAL COSTS(1)

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INTRODUCTION

The costs of appraisal sometimes approach half of the total quality costs. Although most quality cost improvement programs properly concentrate on reducing failure costs first, programs for appraisal cost improvement can also have a significant impact. We will discuss several techniques for improving these costs.

- . Inspection and Test Planning
- . Equipment and Methods Improvement
- . Statistical Quality Control
- . Appraisal Accuracy Studies
- . Decision Analysis
- . Work Sampling

INSPECTION AND TEST PLANNING

Getting the most out of the available appraisal resources requires careful planning. Determining where control points should be and the amount of inspection and test to do should be the job of professionals - not left to the judgment of the individual doing the inspection or test job.

In-process controls are a vital part of a prevention oriented quality system. They provide a powerful means for reducing the incidence of defective finished product and for reducing quality costs. In addition, an effective in-process inspection system often makes it possible to reduce the amount of final inspection required. In-process inspection control involves inspections or verifications performed at significant stages of the manufacturing process. If defective parts or subassemblies are being produced, the trouble can be detected early and corrected before it affects the quality of the finished product. The system must be efficiently designed so that every inspection will serve an essential purpose.

The requirements that the finished product has to meet, along with finished product inspection and test specifications, should be thoroughly reviewed during the development of the in-process inspections and controls. This review provides the Quality Engineer with the information needed to determine the type and degree of in-process inspection required at various stages of the manufacturing process or assembly operations. It also helps him select the kinds of in-process controls that will prevent the manufacture of defective product and yield the best economic return. A periodic review of the planned inspection and tests should be made to assure that the levels remain economical in light of quality history. We will briefly review five types of inspection and test controls and the advantages and disadvantages of each:

- . Operator Inspection
- . 100% In-line Inspection
- . First Piece Inspection
- . Patrol Inspection
- . In-Process Acceptance Inspection

Operator Inspection

In-process controls can be enhanced by requiring an operator, stationed at a machine or at a processing station, to inspect his own work. The operator must be provided with the proper gages and be instructed in their proper use. He should be trained to recognize when an item is unacceptable in appearance. Enough time should be provided in his work standards to allow him to perform the inspection with reasonable care.

These are the advantages of operator inspection:

- . The operator usually handles every piece coming off the line.
- . He is thoroughly familiar with the item he is making.
- . He is in a position to spot defects quickly and call for help to correct problems as soon as they appear.

One caution is that special care may be necessary for the operator to keep the records normally required for an effective inspection procedure.

100% In-Line Inspection

Inspection or testing may be carried out on a 100% basis at designated points in the manufacturing line. This type of inspection or testing is normally performed by inspection or test personnel in the Manufacturing Department. Its purpose is to screen out items that either do not conform to quality workmanship standards or are not likely to pass the finished product inspection.

The following are some of the advantages and disadvantages of 100% in-line inspection.

Advantages

- . It saves the cost of further processing of a product that is likely to fail final inspection and test.
- . It provides data on quality performance that can be used to take corrective action.

Disadvantages

- . The in-line inspection function may become a routine step in the manufacturing line and because the rejects are being screened out, there may be less emphasis on the prevention of defects.
- . It tends to duplicate inspection and increase inspection costs.
- . It is not 100% effective because performing 100% inspection does not guarantee that all of the defective items will be detected.

First-Piece Inspection

In first-piece inspection, several pieces at the beginning of every new run are inspected to determine whether the set-up has been properly made and whether the tooling is adequate. The sample should provide a complete check of the machine or operation set-up. If the machine has nine spindles, for instance, samples should be taken from each spindle. Usually, the first five pieces produced by the new set-up constitute a large enough sample.

The advantage of first-piece inspection is that since the items turned out by a process or operation are evaluated at the beginning of the run, any necessary correction can be made before the run is started.

Patrol Inspection

The inspector patrols the operations at periodic intervals and inspects the items being produced. Since inspection is performed concurrently with the operation, patrol inspection can provide faster response than inspection after the item has been completed.

It is advantageous to use patrol inspection under the following conditions:

- . When a process turns out a high percentage of defective products and requires frequent inspection.
- . When a process is erratic and the operator is unable to do a thorough job of inspection.
- . When there is a need to collect special detailed data on the performance of the process.
- . When an audit of the process is required.

In-Process Acceptance Inspection

This is the classic type of inspection. All the items made at an operation in a given period of time are inspected together as a lot. They must be inspected before they are approved for release to the next operation.

In-process acceptance inspection provides several advantages:

- . It makes it possible to control the quality level at each successive stage of the manufacturing process.
- . It provides data to use in preparing performance reports to help pinpoint problem areas.

On the other hand, it also has some limitations:

- . It does not prevent defects since the inspection is performed after the items have been completed.
- . It delays the movement of parts from one operation to the next.
- . It is not easily applied to continuous processes.

Of the five types of inspection, none is completely effective by itself. An efficiently designed in-process inspection system requires several of them in combination. How they can best be combined to serve particular needs depends on an evaluation of the following factors:

- . The cost of each type of inspection.
- . The type of manpower each type requires.
- . The history of quality performance. Has the process been in control in the past?
- . The type of process. Is it continuous, or can the items produced be collected and inspected in batches?
- . The stability and the capability of the process.
- . The nature of the product characteristics being controlled. Are the characteristics critical or minor?

IMPROVING EQUIPMENT AND METHODS

Many of the most profitable areas for savings of inspection and test costs lie in improved equipment and methods used to do the job. Since inspection and test are not usually measured and controlled to the extent production jobs are, they are not usually too efficient. Improvements can often be made by:

1. Providing equipment which can perform inspection and test tasks faster or without operators.
2. Building inspection or test devices into production equipment.
3. Designing improved record and reporting systems which require less time and effort.
4. Applying industrial engineering techniques to improve inspection and test station layouts and methods.

STATISTICAL QUALITY CONTROL

Powerful tools that can be used to help achieve in-process control are capability studies, control charts and sampling inspection.

A capability study shows whether a machine or process is inherently capable of turning out items that conform to specification. The results of the study may even indicate that it is possible to reduce the amount of inspection without adversely affecting quality. On the other hand, a capability study may reveal

that a certain percentage of the items will always exceed the tolerances of the specification. In this case, it may be necessary either to relax the tolerances or to acquire a machine that is capable of meeting them.

Control charts are another excellent tool for increasing the efficiency of the in-process control techniques. In any series of measurements, there is variation. Sometimes the variation is only the natural outcome of "constant causes" inherent in the process. In other situations, there is also variation due to what are called "assignable causes". In the first case, the variation is normal and the process should be left alone. In the second, the variation indicates that something has gone wrong with the process and action should be taken to correct it. The problem is to decide which type of variation is present.

Acceptance sampling techniques provide a means of measuring and controlling quality without the necessity of checking all the units produced. By using a sampling plan, it is sometimes possible to significantly reduce the costs associated with appraisal while still maintaining adequate control.

ACCURACY STUDIES

There are failure costs associated with incorrect quality decisions on the part of inspectors, testers, or operators. These can be in the following areas:

1. Falsely rejecting acceptable material.
2. Falsely accepting rejectable material.

There are many plans which rate appraisal personnel in relation to these two errors. Perhaps the easiest to apply is one involving accuracy as a percent of defects correctly identified. This involves submitting a known number of good and bad units to an individual and rating his ability to correctly separate the units. The number of incorrect decisions is then multiplied by the cost of each wrong decision and an extension is made showing the cost implications.

DECISION ANALYSIS

In the early manufacturing of a new product (and in spite of good quality planning), the need for adjustment of measurement and test controls is generally revealed. This creates a need to analyze the effectiveness of decisions made on components, sub-assemblies and final product in terms of the earliest possible detection of defects. A technique called decision analysis is sometimes helpful in such a determination. This involves an analysis of accept-reject decisions of inspectors and testers, and identifies the point in the process where such decisions are made. Further, the model or part on which such decisions are made is also specified.

Summaries of such results frequently show trends for individual inspectors, especially where inspection planning, visual standards or training is less than adequate. These trends show up in terms of two inspectors servicing the same area and rejecting significantly different amounts of material. Also, decision times (i.e., the time required to make an accept-reject decision) may be significantly different for two inspectors in the same area.

Obviously, the planning engineer must address to these differences and provide improved control (and therefore improved costs) by more effectively utilizing the appraisal personnel.

WORK SAMPLING

The technique of work sampling consists of sampling work elements of an individual or group and using probabilistic theory to estimate the total time spent on a given activity. When applied to appraisal personnel, who very often do not have repetitive work elements, it can be used to more effectively structure the work routines. For example, if work sampling determines that 10% of an inspector's time is spent walking from one end of the department to another, then obviously some change in his geographic assignment or work station could be made to minimize such a cost.

Generally, work sampling has been found to be a better tool for measuring indirect labor rather than direct labor, inasmuch as repetitive work elements can be studied by either time study or predetermined time standard systems.

REDUCING APPRAISAL COSTS

In summary, we can (and should) ask some pertinent questions to determine the effectiveness of our appraisal efforts:

1. Are inspection points located to maximize the return on dollars spent for inspection?
2. Are inspection stations and methods engineered for the most efficient work accomplishment?
3. Could inspection and test operations be economically automated by using special purpose instrumentation, or tape or computer controlled equipment?
4. Could inspection and test record and data reporting functions be more efficiently performed using the computer or other modern data handling devices?
5. Is it possible to control processes sufficiently to prevent production of defectives and eliminate product inspection?
6. Could statistical Quality Control techniques be profitably used?
7. Could tests now being performed by outside laboratories be performed at less cost in-house or vice versa?
8. Are some tasks now being performed by highly paid inspectors or testers which could be performed by lower classification employees?

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LCS 350:10:000

REDUCING FAILURE COSTS AND MEASURING IMPROVEMENT

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Today I would like to discuss with you two topics — reducing failure costs and measuring improvement — from the ASQC publication "Guide for Reducing Quality Costs." Reducing failure costs is a tough thing to do and I am sure you will agree that once it is reduced, it is even tougher to maintain the new level. Eliminating failures is something like an old leaky tube of toothpaste. You can fix the leak and force the toothpaste in the right direction — through the nozzle; but not for long — soon it leaks in another spot. But there is a reason for this. It is because in most cases the real cause of the problem has not been identified. Without knowing what the real problem is, we surely can't fix it.

So often the quality manager sees his job only as informing management of symptoms of problems such as high rejects and excessive returns from the field. His fix, considering his perceived scope of activity, is to put more inspection on to keep the bad parts from escaping until that day comes when the problem is corrected. But without effective corrective action that day never comes. Management looks to the quality organization for more than this and rightly so. The quality organization must not only report problem symptoms, it must involve itself in the mainstream of defining the real problem and proposing the best possible solution. The quality organization must develop an effective corrective action system that gets at the root cause of problems in order to permanently reduce failure costs.

The ASQC publication "Guide for Reducing Quality Costs" recommends four key ways of reducing the cost of failures. These are to:

- Communicate the problem area to all affected persons.
- Create a desire in others to mutually solve the problem.
- Provide leadership in the planning and carrying out of a logical investigation by those in the company best able to resolve the problem.
- Follow up to insure that the problem was permanently fixed.

Quality performance reports are a good tool for communicating problem areas to those that can solve the problem and to make top management aware of the progress. However, they must be understandable, clear and to the point. They should summarize information and not overwhelm the user with needless detail, while pointing out and emphasizing the significant trends. Certainly, the reports should be designed to meet the needs of those using it for taking corrective action, as well as for those tracking the progress. Obviously, there is no one best format; the reports must be individually designed to meet the needs of your organization. They must be user oriented. If they are not they will be useless documents on the desks of those people that the quality manager needs most — those that can find and fix the problem.

Creating a desire in others to mutually solve a problem is critical for most quality managers. It is directly reflected in the quality manager's ability to solve the chronic quality problems existing in his company. This is because the causes of the chronic problems are not normally the ones that the quality manager can correct by himself. A chronic problem may be caused by bad designs, improper tooling, improper manufacturing sequences or many other things which, of course, must be corrected by someone else. To get someone else to do something about the problems is a selling job, to a large extent. For the quality manager this involves selling himself, his corrective action program and, most importantly, the fact that the problems are serious enough to justify spending the time and money necessary to solve them.

It is important to remember that in order to effectively sell your programs, good justification must be the corner stone. In the early stage of investigation the cost of the problem, the amount of effort needed for solution and the tangible and intangible benefits should be estimated as best you can and presented in your corrective action reports. Adequate justification will gain support from your management when the problem is stated in terms they understand. For example, the engineering department can often be stimulated to correct a design problem when it is shown that it affects product reliability and that a specific amount of excessive warranty cost is being generated. The production supervisor must be convinced that a solution to a rework problem will help him in his daily battle with the efficiency of his operation. Above all, don't give up if your best selling job falls on deaf ears the first time around. If you are still convinced that the solution to the problem will contribute positively to your company, look for ways around the road blocks. Remember, the quality manager must provide the leadership for failure reduction.

Of course, a key to your failure reduction program is a systematic corrective action system through which logical investigations and resolutions of problems can be processed. The ASQC publication "Guide for Reducing Quality Costs" suggests several forms that can be used as a framework around which your system can be designed. Experience has shown that certain aspects need to be determined and documented early to insure the effective operation of your system. They are:

- A step-by-step plan for investigating and solving the problem. Each step should have the responsible individual listed along with a target date for completion. It is vital that the plan be kept up to date, reflecting changing conditions, and that periodic status be reported.
- Both tangible and intangible benefits expected to be achieved in terms management can understand.
- The projected cost to achieve the desired results.

By having a plan, those involved will be confident that progress will be made and that the benefits at the end of the road outweigh the costs that will be incurred along the way. In addition, priorities can be systematically assigned to problems so that those having the greatest benefit to your company will be attacked first, while those having smaller payoffs wait on the back burner.

Following up to insure corrective permanent action boils down to a periodic measurement of the results. The initial measurement will determine if the plan is achieving the projected results at the estimated cost. If it did not, additional investigations to obtain the needed results should be launched. Periodic remeasurements, either as part of your formal quality reporting system or by special studies, will help insure that the gains are permanent. Holding the improved quality levels is vital and often overlooked. It is common to see improvement trends reverse themselves and head toward former levels. By proper reevaluation, these downward trends can be caught early and corrected before they become serious.

In summary, a program to reduce failure costs has to consider:

- Communication of problem areas to all those affected.
- Creating a desire in others to mutually solve the problem.
- Providing leadership in the planning and carrying out a logical investigation of the problem with those best able to resolve the problem.
- Following up to insure that the problem was permanently fixed.

Now let us discuss our next topic, which is included in the ASQC publication "Guide for Reducing Quality Costs," how can we measure improvements in a company's quality system? Being a quality cost session, you might think that we would stress that quality cost is the best way of measuring improvements, but this is not always true. Only sometimes can quality cost provide the answer and, when it is used, it must be applied with a great deal of care and discretion. The ASQC publication "Quality Costs - What and How" is a good reference

to help you stay clear of the pitfalls inherent in comparing costs.

For example, don't be misled in comparing percentages. One might assume that a failure cost decrease from 70% of total quality cost to 60% is a big improvement. But if total quality cost, on a unit basis, rose between the two periods from \$2.00/unit to \$2.50/unit due to added inspection, failure cost on a unit basis actually increased. Indeed this company is still in trouble. Quality costs are usually good for determining the magnitude of in-plant improvements that require the measurement of inspection, scrap or rework costs. But again, be careful. Don't make conclusions on records alone — use personal observations too. Take a walk to the production line and see if things are what the records indicate. So often an innocent mistake in recording information or a major shift in the product mix to something easier to build will cause results on paper to misrepresent what is really happening. There is really no substitute for a first hand look at the situation.

Perhaps the greatest pitfall to guard against in using quality costs is to measure the effect of product improvements relative to field failure or warranty. To illustrate this, let's suppose that we have a reliability problem that only shows up after six months in the customer's hand. Assume that we fixed that problem in January, 1978. Even if the product goes directly to the customer, it is July of that year before the effect on warranty cost is felt. Obviously, it is absurd to use warranty expense for the month of May to track the difference. This inherent lag makes it tough to apply quality costs to finding out if field performance is better, especially if your boss is breathing down your neck for an answer. Something else must be used to obtain timely answers such as life cycle testing or possibly outgoing quality audits of completed products that incorporate durability provisions. Such tests can discover system or product discrepancies far more quickly and at less expense than would be associated with waiting for failures in the customer's hands.

Other sources of data besides warranty failure costs that are good indicators of field performance, depending upon each individual situation, are:

- Field trouble reports originated by perhaps your field service engineers. These provide more detail regarding your quality problems allowing a more accurate comparison between present and past performance.
- Market research surveys that determine what the customer thinks about your product. This indeed may be an appropriate way of getting a handle on potential lost sales due to quality problems.
- Spare part sales that supplement warranty failure cost information may better identify product performance trends.
- Customer complaints, properly tabulated and summarized, are another means of tracking progress. However, caution must be exercised in that this data may not represent your normal customer — they usually are from the most irate of customers.
- Installation phase reporting of quality problems found in the erection and commissioning activities of large and complex projects certainly is a valuable source for tracking progress for these type of products.

In summary, there are many ways besides quality cost to track improvements in a company's quality system. The choice of which method or methods to use depends upon your individual situation. One method that is inadequate for one situation may be the best in another. Most importantly look before you leap. Carefully look at all the alternatives before selecting those that you will use for your immediate needs.

DLA CONTRACTOR ASSESSMENT PROGRAM

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INTRODUCTION

In January 1975, the Defense Logistics Agency (DLA), at the request of the Department of Defense (DoD) Quality Assurance Council, undertook the task of developing a concept for certifying defense contractors with superior quality history. After evaluating certification programs utilized by other government agencies, NATO countries and private industry, a plan was formulated which combined the best features of all the techniques considered as well as others developed by DLA. The basis for the plan is predicated on the DoD philosophy of quality assurance, which states that responsibility rests upon the supplier for the quality of their product and that utilization of Government Quality Assurance personnel must be prioritized based on the contractor's demonstrated control of product quality and the effectiveness of his quality system. The concept, covering most DoD procurements, was approved in April 1976 and steps were taken by DLA for a trial implementation at select contractor's plants starting in November 1976.

INITIAL SELECTION OF CONTRACTORS

In the selection of contractors for trial implementation, Phase I of the test program, DLA considered only prime contractors who: (1) met the requirements of military specification MIL-Q-9858A, which requires the contractor to establish an effective and economical quality program throughout all areas of contract performance; (2) had inspection and acceptance at source; (3) met the rigid selection criteria; and (4) had a history of delivering superior quality products. After carefully evaluating the possible participants, the RCA plant at Morrestown, New Jersey and the Bendix plant at Towson, Maryland, were chosen as sites for the test.

The senior executives of RCA and Bendix agreed to participate in the test program. Their commitment to the program was on a strictly voluntary basis and with the understanding that no contractual changes would be made, no overall increases in costs would be incurred, the program could be terminated at any time by the contractor or the government without prejudice, and the number of government personnel at the facility would be reduced to a minimum consistent with the quality of the products and the overall government quality assurance in-plant workload. This in no way infers that there would be an abrupt removal of Government personnel from a contractor facility. Rather, a Government Personnel Plan is developed for the facility and takes into consideration the manpower and skills requirements geared to the tasks to be accomplished. Thus, the reallocation of resources, if necessary, is gradual and then only to concentrate it more efficiently in other quality areas, similar to that which occurs as a result of normal workload expansions and contractions.

GOVERNMENT QUALITY ASSURANCE PLAN

The main thrust and heart of the program is the tailoring of a detailed Government Quality Assurance Plan to the facility, its programs and products. The plan provides for verifying the contractor's control of quality as well as an independent evaluation of the quality of products. It further provides for the maintenance of sufficient objective quality evidence which will provide traceability and for the continuous tracking and use of quality data to determine effectiveness and adequacy of the quality program.

The Government representative responsible for planning, developing, implementing the contractor Assessment Program (CAP) at a given contractor facility is identified as the Government Quality Assurance Manager (QAM). This title was selected to emphasize his greater responsibilities, considerably broader and more demanding than those of the typical DLA Quality Assurance Representative. Cooperation between the Government and the contractor is stressed in developing a Government Quality Assurance Plan that will assure effective control in a plant. The monitoring and review functions performed by the contractor in accordance with specification MIL-Q-9858A, Quality

Program Requirements, are primary considerations. The plan describes quality tasks that are important to overall quality in the plant; the procedural aspects as well as the person or organization responsible for each of these tasks; the manner in which the contractor will perform his monitoring and review actions; and how the Government will verify those actions. The frequency of Government verification is determined by the extent of control exercised by the contractor.

IMPLEMENTATION AND RESULTS OF PHASE I

The trial implementation of the Program at RCA and Bendix began in November 1976. Comprehensive data was collected and analyzed biweekly, historical data was compared with test data. The overall analysis of Phase I was made in July 1977 by DLA and representatives of the military departments and found to be working satisfactorily; that the program was effective in meeting its objectives; and that it had the potential as a viable management tool for both government and industry. It clearly illustrated the benefit of the program in terms of the increased efficiency of contractor line inspectors and the lower percent of defective items found by the company's quality auditors during their subsequent examination of the product. The number and severity of defects found by the inspectors and auditors over a six-month period provided a good measure of product quality inasmuch as they are quality indicators that can be easily understood and analyzed. Results of Government product verification and evaluation of the contractor's quality procedures during the same period significantly reflected the overall improvement in quality at both test facilities.

Because the major programs at the two test facilities were developmental in nature rather than production oriented, the decision was made to extend the test over a longer period of time and to include facilities with production contracts in order to determine the true worth of the program. Field usage, the ultimate yardstick by which product quality can be measured and user satisfaction determined, was not available during Phase I of the test because of the nature of the contracts at RCA and Bendix, but will be under the expanded version of the program. The program was implemented on one product line at Texas Instruments, Dallas, Texas, in May 1977 and analysis of the results disclosed that it is working well there.

IMPLEMENTATION OF PHASE II

Phase II of the test program was implemented in early 1978 and will extend into 1980. It was determined at the onset that a select number of facilities with production contracts would be added to broaden the data base and make it possible to assess the quality and reliability of fielded material that might best be approached by reviewing available field user data. Such participation should contribute in an important way to the determination of user satisfaction and at the same time provide the opportunity for a shakedown and refinement of the procedures, if necessary, which will give both Government and industry the added confidence to proceed with the program.

The Cleveland Pneumatic Company, Cleveland, Ohio, a company which produces landing gear for military aircraft and with a history of outstanding quality products, was the first production facility to be considered for the Phase II extended test. The program was implemented there on 1 March 1978 and results thus far indicate that it is proceeding satisfactorily. Others will be brought into the program as rapidly as possible. It is expected that the military departments as well as the DLA Contract Administration Regions will recommend contractors for inclusion in the Program. Final selection will be made by the Contractor Assessment Board (CAB) which is composed of senior quality representatives of the military departments and DLA. Candidates will be selected on the basis of restrictive qualification criteria, primarily an established history of high quality performance. A survey to determine any adjustment in government manpower needs is conducted six months after implementation of the program in a facility, commensurate with the contractor's level of performance over that period of time. A semi-annual evaluation of each contractor's performance will also be made by the CAB with summaries of quality data furnished to government Program Managers every three months. A follow-up quality system review is conducted at all CAP facilities 12 months after implementation to determine the effect to the program on product quality.

The CAP can be advantageous to both Government and industry. Participating contractors, through encouragement to improve the quality of their product, will be

STANDBY SPEAKERS

rewarded with greater production efficiency. The program has promise for cost reductions and improved efficiency in Government quality assurance. It is expected to play a significant role in the shaping of quality and reliability programs of the future, and has the potential and promise for the next major advance in procurement concepts.

LCS 310:70:991

FABRICATION INFORMATION SYSTEM

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INTRODUCTION

The Fabrication Information System was designed as an aid to Product Assurance personnel in the collection of quality data in various areas of the Fabrication Shop, in order that predominant problem areas be readily recognized. The purpose of the system is to: (Figure 1.)

- a. Collect yield data.
- b. Provide on-line visibility of defect data.
- c. Issue periodic reports to cognizant responsible personnel, summarizing defect data.
- d. Calculate and display Process Control Limits (PCL) for any part number in the system.
- e. Allow the on-line application of Process Control Limits based on the previous 52 week period.
- f. Obtain appropriate corrective action as necessary, if the process exceeds the calculated limit based on the capability of the process.

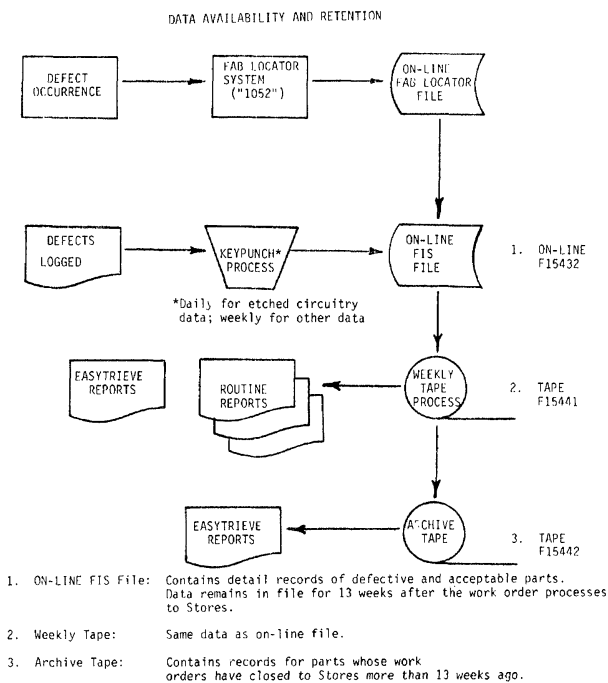


FIGURE 1

The quality history information sources for the system files are the Fabrication Information Log (Figure 2) completed by the floor inspectors daily for all work orders processed through each inspection station, including the Material Review area.

FABRICATION INFORMATION SUMMARY

No. 000737

CONTROL CENTER

MEM
MEM

FABRICATION INFORMATION SUMMARY

[illegible]

FABRICATION INFORMATION SUMMARY FORM COMPLETION INSTRUCTIONS

GENERAL

1. The FIS is used to record quality-provided defect areas in all areas of the fabrication shop, except the TOW, Etched Circuitry and Soldered areas.
2. The FIS is completed (items 3-10) by Floor inspectors when
 - a. A shortage (loss) or average (gain) of parts has been identified
 - a QST has been generated for setup
3. The FIS is completed (items 3-10) by Material Review Inspectors when
 - an HCMR has been processed
4. FIS sheets are picked up by Fabric Production Assurance Supervisor at the beginning of each shift. The sheets are processed by the Material Review Inspectors. The sheets are promptly returned to Product Assembly Control for processing into the data system.

COMPLETION INSTRUCTIONS

- | | |
|---|--|
| Completed by Product Assurance Supervisor with current manufacturing work file. | Completed by Product Assurance Supervisor with the General Center number and date for responsibility for completion of the form. |
| The work order number assigned to this job order. | The operation number where the defects were found. |
| The quantity of defective parts corresponding to this disposition (sum). | "1", if the defects were found at an initial inspection; "02", if the defects were found after they were resorted (i.e., at reinspection). |
| The code corresponding to the disposition of the defective parts. | O: Stop number (reject stamp), only required when a disposition of "Stop" is made. |
| The QST or NCMR number when the disposition was made. Cross out "N", if a QST number is entered; cross out "Q", if an NCMR number is entered. | The appropriate defect code for the defective parts. Up to 4 codes may be specified for a given disposition. |
| No Entry | No Entry |

CODES USED FOR THE FORM:

DISPOSITION CODES		DEFECT CODES	
A	Repair Complete	HOL	Hole
B	Use As Is	CON	Concentricity
C	Use As Is	PAR	Parallelism
D	Standard Repair	DMC	Damage
E	Repair to Material	COM	Comer
F	Repair to Material	SUR	Surface
G	Lost	SUS	Suspect
H	Lost	OTH	Other
I	Over	GRD	Grind
J	Over	RAD	Radius
K	Over		
L	Over		
M	Over		
N	Over		
O	Over		
P	Over		
Q	Over		
R	Over		
S	Over		
T	Over		
U	Over		
V	Over		
W	Over		
X	Over		
Y	Over		
Z	Over		

Figure 2

Information concerning the quantity and configuration of the items in the work order moved between operations is supplied by the Fab Location System upon update by Production Control personnel. Defect information is recorded on the appropriate summary logs by Fab inspectors under the Quality Department direction and batch processed into the system files daily via various satellite CRT terminals strategically located within the facility.

Data fed into the system is maintained in the on-line files, allowing interested persons to easily obtain history on a given part number and operation number. The on-line CRT screens may be updated too, for instance, add corrective action narratives to the files for a specific lot of parts.

Control limits are directed under the cognizance of the Product Assurance Fab Engineering group and may be of three types:

- a. Percent fraction defective. (\bar{P})
- b. Defects per unit.
- c. Engineering action limits.

Percent fraction defective control limits are developed utilizing available historical data to establish a long term average where X is the number of standard deviations in the formula:

$$UCL = \bar{P} + X \sqrt{\frac{\bar{P}(1 - \bar{P})}{N}} \times 100$$

Initial control limits were established based on 13 weeks of fabrication history after manufacturing techniques, methods, and tooling had been established. The machines used were dedicated to a specific aerospace program and were operated on a 3 shift basis performing repetitive operations. The majority of the machines utilized were NC tape operated or controlled mechanically by fixed cams and templates to control the necessary machine functions for the machining operations. Various functions performed by the machines were turning, milling, drilling, tapping, and boring. Many of the drilling and tapping operations were "ganged" and all holes drilled and tapped simultaneously. Tolerances varied in the range of from .00005 for critical gimbal bearing bores up to + .010 for the numerous various characteristics. Many of the parts were machined from aluminum preforms, bar stock, or extrusions. Hand, and vibratory tumble deburring was performed.

An excerpt from a typical EDP Summary Report (Figure 3) summarizing all of the part numbers fabricated for the past 52 weeks listed by operation, lot size, quantity suspended, and the calculated process average (\bar{P}) is updated each 13 week period. The responsible Product Assurance engineer reviews this data to determine which data should be discarded from the process average because of it not being normal to the manufacturing process. Data eliminated includes machine/fixture malfunctions, operator error which affects a large portion of the work order before being recognized, tool breakdown or any variation not normal to the established manufacturing process.

REPORT PROGRAM		1543-F HAYM		FAB CONTROL LIMITS		FOR 40/76 THRU 39/77			
PART	OPER	WW	INSPECTED QTY	SUSPENDED QTY	PCNT SUSP				
3227580-1-1	0105	42	212		.00				
		43	506		.00				
		44	250		.00				
		46	261		.00				
		47	49		.00				
		50	245	3	1.22				
		07	195		.00				
		08	169		.00				
		10	503		.00				
		12	231		.00				
		13	19		.00				
		16	10		.00				
		22	2		.00				
		23	15		.00				
		26	459		.00				
		30	2		.00				
		36	240		.00				
		37	175		.00				
		39	75	75	100.00	(OPERATOR ERROR)			
			3618	78	LTA-	2.16	PPWK-	190.4 UCL-	5.31 **

FIGURE 3

A report is then issued each 13 week period (Figure 4), listing corrected \bar{P} which reflects the normal variation expected from the machining process. This tabulation is utilized by the Product Assurance floor engineer, in conjunction with the Product Assurance Allowance Table (Table I), to determine the necessity for corrective action as the discrepant material is reviewed.

PART NUMBER	OPERATION	\bar{P}	CONTROL LIMIT \bar{Z}		
			NEW	OLD	USE (WM 27-39)
Housing, Electronic	20	0.5			
	30	0.5			
	40	0.5			
	50	6.0	10.7	10.3	10.3
	60	0.5			
	70	1.4			
	80	0.5			
	100	0.5			
	110	0.5			
	120	0.5			
	125	1.4			
	130	0.5			
Nose, Cover					
	3227225-1-1	30	0.5		
		40	0.5		
		50	2.1		
		60	0.5		
		65	0.5		
		70	0.5		
		80	0.5		
Gimbal, Outer					
	3227315-1-1	20	0.7		
		30	0.9		
		30A	1.7		
		30B	1.0		
		40	1.3		
		50	0.6		
		60	0.5		
		70	2.5	5.2	5.2
		80	0.9		
		90	0.5		
		100	2.8		
		110	6.7	11.7	8.5
		120	1.9		
		125	0.5		

FIGURE 4

TABLE I

PRODUCT ASSURANCE ALLOWANCE TABLE

THIS TABLE MAY BE USED FOR APPROVED CONTROL LIMITS ONLY

LEVEL \bar{P} (%)	2 σ STANDARD DEVIATION									
	ALLOWABLE PARTS DEFECTIVE/WORK ORDER SIZE									
	1	2	3	4	5	6	7	8	9	10
0.5	34	107	200	306	421	542	669	801	936	1074
0.6	28	89	167	255	351	452	558	668	780	896
0.7	24	76	143	218	301	387	478	572	669	768
0.8	21	67	125	191	263	339	419	501	585	672
0.9	19	59	111	170	234	301	372	445	520	597
1.0	17	53	100	153	210	271	335	401	469	538
1.1	15	49	91	139	191	247	305	364	426	489
1.2	14	44	83	128	175	226	279	334	391	448
1.3	13	41	77	118	162	209	258	309	361	414
1.4	12	38	71	109	150	194	239	287	335	384
1.5	11	36	67	102	140	181	224	268	313	359
1.6	10	33	63	94	132	170	210	251	293	337
1.7	10	31	59	90	124	160	197	236	276	317
1.8	9	30	56	85	117	151	186	223	261	299
1.9	9	28	53	81	111	143	177	211	247	284
2.0	8	27	50	77	105	136	168	201	235	269
2.1	8	25	48	73	100	130	160	191	224	257
2.2	7	24	45	70	96	124	153	183	214	245
2.3	7	23	43	67	92	118	146	175	204	234
2.4	7	22	42	64	88	113	140	168	196	225
2.5	6	21	40	61	84	109	134	161	188	216
2.6	6	20	38	59	81	105	129	155	181	208
2.7	6	20	37	57	78	101	125	149	174	200
2.8	6	19	36	55	75	97	120	144	168	193
2.9	6	18	34	53	73	94	116	139	162	186

USE 1. Locate the approved long term average percentage (\bar{P}) in the left hand column.

2. Find the work size or the nearest lower number under the adjacent right columns.

3. Determine the allowable parts defective at the top of the column.

LEGEND \bar{P} = Long term average percent defective.

Since the reporting function for each operation includes all discrepant material including set-up scrap, it was arbitrarily decided that .5% defect per work order would be the minimum acceptable process average below which corrective action would not have to be taken.

If there is no reason to believe that any of the manufacturing process has significantly changed, \bar{P} is a reasonable estimator of the fraction defective for the lot fabricated.

Since the sampling technique of the work orders sorts the nonconforming units taken randomly from the lot, it has at least one of the principal requirements of a binomial distribution. Samples contain acceptable or nonconforming pieces. Samples taken from successive lots using the same or similar manufacturing techniques will have a characteristic central tendency but will also have a characteristic dispersion. The more defectives, the wider the dispersion. As one might expect, the smaller the number of defectives in the lot, the narrower the dispersion.

To assist the Product Assurance engineer on the floor in determining the need for corrective action when reviewing the Quality Status Tag which documents any discrepancies in the work order, it was necessary to devise a rapid method to know if the manufacturing process for that operation was in control based on the past manufacturing history.

The Allowance Table (Table I) was devised by utilizing the basic equation for calculating the control limits for a P chart by substituting in the equation the permissible number of defectives from 1 to 10 in any lot for any long term average percent defective. By solving the equation for N and then rounding, the lot size was readily determined for any \bar{P} . The allowable parts defective chart versus the work order size was tabulated and was readily available for the supporting engineers use. The calculations were performed on the computer and listed the maximum number of defectives allowed in a work order for any \bar{P} . Any time the number of defectives in a work order exceeded that allowed by the table, the cognizant Product Assurance engineer would investigate to determine the exact cause and obtain the appropriate corrective action. Action limits were established at 2 standard deviations where corrective action was necessary.

Since the reporting function readily distinguished the problem areas, a concerted effort was expended on the worst ones first to determine the cause of the repetitive discrepancies in order that the appropriate corrective action be taken.

After obtaining an acceptable level, the operation with the next highest discrepancy rate was investigated until that operation was brought into control. Thus within a reasonable length of time, all operations were running with an acceptable percent defective.

This Fabrication Information System has been in operation for approximately 3 years. During this period of time, the data collected from this system has identified numerous potential/actual problem areas. These problems were investigated by the Fabrication Product Assurance Engineering organization and the cause of the problems were isolated. The responsible cognizant organization was then notified and the appropriate corrective action was initiated. The data was monitored to assure that the corrective action was effective.

A Fabrication Quality Report consisting of three sections is issued weekly. Section I contains the list of Part Number/Operation Number which will be reported on for the present quarter. Control limits are shown with their respective Part Number/Operation (Table II). Part numbers are reviewed quarterly and those which are designated by the responsible Fabrication Product Assurance engineer are included on the list. The Control Status column indicates the number of consecutive weeks the Part Number/Operation has exceeded its control limit.

TABLE II

Part Number	Oper. No.	Qty In W.O.	Qty Susp.	% Susp.	Control Limits	Control Status
3227221-2-1	050	0	0	---	1.9	
3422667-1-1	057	243	0	0.0	2.3	
3422667-1-1	060	100	0	0.0	1.2	
3422673-1-1	020	48	0	0.0	1.1	
3422673-1-1	030	0	0	---	2.0	
3422673-1-1	120	98	3	3.1	2.9	OUT
3422673-1-1	130	51	0	0.0	1.3	
3422673-1-1	135	47	0	0.0	3.2	
3422673-1-1	160	46	0	0.0	2.4	
3422673-1-1	180	0	0	---	1.6	
3422674-1-1	150	321	3	0.9	1.1	

Section II, as a minimum, contains statement of cause and corrective action for all Part Number/Operations (Figure 5) which have exceeded their control limits for 3 consecutive weeks and will be reported in the following weeks report, along with their trend charts. Normal corrective action is accomplished by applying the upper control limit on a case by case basis during the daily production activities.

REF: TQP 1.5.101 Control Limits - Development and Applications

The Part Numbers/Operations listed on the following pages indicate an acceptable quality attrition level for operations being performed on Maverick missile fab items in consonance with the requirements defined in the referent TQP.

The attrition levels shown, generated by the Fabrication Information System, are long term fraction defectives (\bar{P}) calculated from data between WW 14, 1976 and WW 13, 1977 on a weekly basis with the corresponding calculated 3σ control limit where applicable. The next reevaluation will be made WW 27, 1977.

All operations show a decrease in the \bar{P} or have remained at a low constant. The tabulation for P/N 3227580-1-1, Operation 105, indicates that since W/W 34, discrepancies have been at a minimum, reflected by the continued reduction in the control limit. Thus, the corrective action taken was effective.

P/N 3240377 - This part has been completely re-planned. Therefore, operation 67 and 68 have been removed from the report and replaced with operation 30 and 60.

Operation 50 (vibratory deburr) has been added to the report due to the high \bar{P} figure (2.2%).

CAUSE: Excessive burrs in slots.

CORRECTIVE ACTION: Media has been changed to vibro-cut pyramids and carpet tacks.

Operation 50 will remain on the report to monitor the effectiveness of the corrective action.

The tabulation, attached, lists the old 3σ calculated control limits that were above 5% in addition to the new 3σ control limit for comparison.

FIGURE 5

Section III contains the trend charts for Part Number/Operation Number listed in Section I. Only trend charts where the Part Number/Operation are out of control will be included. (Figure 6.)

FABRICATION TREND CHARTS

○—○ WEEKLY DATA
— CUM DATA

AREA 5161 MAV MACH SHOP

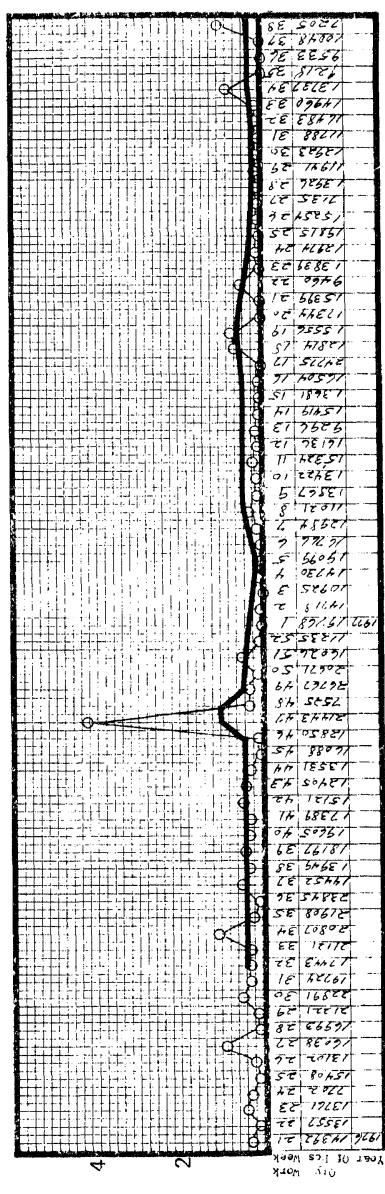
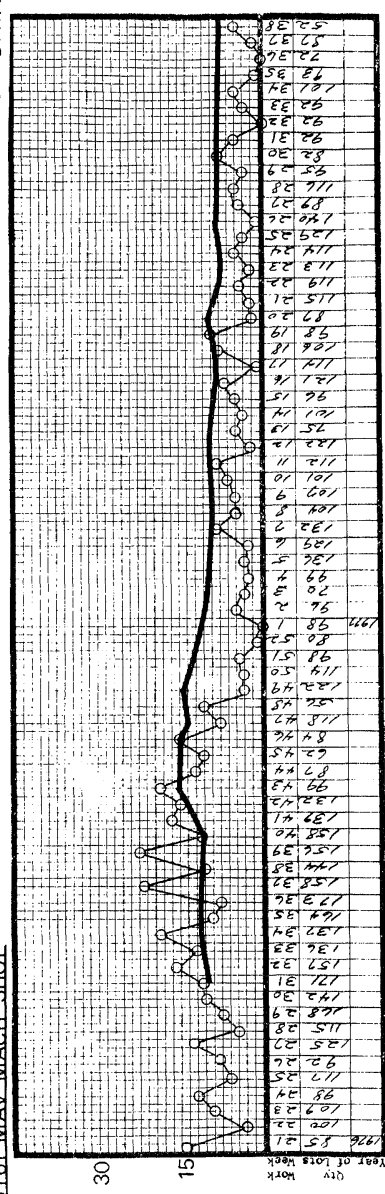


Figure 6

The implementation of this system has contributed to a timely and effective method of identification of defects and the initiation of corrective action for a major missile program. This has resulted in a lower cost of the product because of the reduction in scrap and rework costs.

An effective corrective action program has many benefits other than the obvious one of reducing excessive scrap and rework costs. It improves schedule time, eliminates overhead charges such as handling and storage of nonconforming parts, reduces inspection labor (it is easier to inspect good parts than bad parts), reduces customer complaints, and motivates people to do their best work.

As soon as first line supervision realizes that corrective action is helping them solve line stoppage problems and meet their schedules and budgets, a better relationship has been established between Manufacturing, Quality Control, Engineering, Material Control, Purchasing, and the other departments that convert raw materials into finished goods. The best indication that the program is working is when Manufacturing supervisors begin to solicit assistance from corrective action personnel.

LCS 640:20:400

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1. INTRODUCTION

Most of the control chart procedures assume that the process variability is known or can be estimated with sufficient degree of accuracy from data already at hand. In practice the variance of the process is estimated using sample ranges and sample variances. One of the most frequently used method is to use the sample variance

$$S^2 = \left(\frac{1}{n-1} \right) \sum_{i=1}^n (X_i - \bar{X})^2 \quad (1.1)$$

where n is the sample size and \bar{X} , the sample mean, for estimating the process variance σ^2 . As is well-known, S^2 is an unbiased estimator of σ^2 under the assumption that the observations X_i are independent and identically distributed random variables. In practice, however, the observations from many industrial processes are not independent but serially correlated. This introduces a bias in estimation of σ^2 and also affects control procedures in which the correlation among the observations will have an effect on their optimal properties. Goldsmith and Whitfield [5] studied the effect of serial correlation on the parameters of V-mask for cusum charts. A similar study was done by Hunter and Kartha [6] on the optimum target values of a production process in which observations from Autoregressive and Moving Average models were considered. Also bias in estimating σ^2 for these models was considered which will be discussed in Section 2 of this paper. In Section 3 we will study the effect of this bias on the parameters of a cusum chart under a decision interval scheme.

2. BIAS IN ESTIMATING σ^2

We shall consider the bias in estimating the process variance σ^2 by using (1.1) when the observations are serially correlated. In particular we will consider the situations in which the observations follow either a first-order Autoregressive process (AR(1)) or a first-order Moving Average process (MA(1)). (Box and Jenkins [2]).

(i) AR(1) Process

Suppose observations X_1, X_2, \dots, X_n are from an AR(1) process defined by

$$(X_t - \mu) = \phi(X_{t-1} - \mu) + a_t \quad (2.1)$$

where $0 < |\phi| < 1$ and $\{a_t\}$ is a white noise series, normally distributed with mean 0 and variance σ_a^2 . The vector (X_t, X_{t-1}, \dots) will follow a normal distribution with mean (μ, μ, \dots) and variance covariance matrix $\Sigma = \{\sigma_{ij}\}$ where

$$\sigma_{ij} = \text{Cov}(X_i, X_j) = \phi^{|j-i|} \sigma_a^2 \quad (2.2)$$

and

$$\sigma_{ii} = \text{var}(X_i) = \sigma^2 = (1 - \phi^2)^{-1} \sigma_a^2 \quad (2.3)$$

$$E(S^2) = E\left(\frac{1}{n-1} \sum_{i=1}^n (X_i - \bar{X})^2\right) = \frac{1}{n-1} \left(\sum E(X_i^2) - n E(\bar{X})^2 \right) = \frac{1}{n-1} (n(\mu^2 + \sigma^2) - n E(\bar{X})^2) \quad (2.4)$$

It can be shown that

$$E(\bar{X}^2) = \mu^2 + \frac{\sigma^2}{n} + \frac{\sigma^2}{n^2} \left\{ \frac{n\phi}{1-\phi} - \frac{\phi(1-\phi^n)}{(1-\phi^2)} \right\} \quad (2.5)$$

$$E(S^2) = \sigma^2 \left\{ 1 - \frac{\phi}{(n-1)(1-\phi)} + \frac{\phi(1-\phi^n)}{n(n-1)(1-\phi)^2} \right\} \quad (2.6)$$

It follows from (2.6) that S^2 is a consistent estimator of σ^2 for $|\phi|$ being not close to 1. If $|\phi|$ is near one, for moderately large n , (4.25) would tend to underestimate σ^2 for $\phi > 0$ and overestimate for $\phi < 0$. When $\phi = 0$, S^2 is an unbiased estimator of σ^2 .

(ii) MA(1) Process

Suppose that the observations are from a MA(1) process given by

$$(X_t - \mu) = a_t - \theta a_{t-1} \quad (2.7)$$

where $0 < |\theta| < 1$ and $\{a_t\}$ is a white noise series as defined above. In this case, the vector (X_t, X_{t-1}, \dots) is normally distributed with mean (μ, μ, \dots) and with variance-covariance matrix $\Sigma = \{\sigma_{ij}\}$ where

$$\sigma_{ij} = \begin{cases} -(1 + \theta^2)\sigma_a^2 & \text{if } |j-i| = 1 \\ 0 & \text{if } |j-i| > 1 \end{cases}$$

and

$$\sigma_{ij} = \sigma^2 = (1 + \theta^2)\sigma_a^2 \quad (2.8)$$

As before

$$E(S^2) = \frac{1}{n-1} (n\sigma^2 + \mu^2) - n E(\bar{X})^2 \quad (2.9)$$

and it is shown that

$$E(\bar{X})^2 = \frac{1}{n^2} \{n(\sigma^2 + \mu^2) + 2(n-1)\rho_1\sigma^2 + n(n-1)\mu^2\} \quad (2.10)$$

Substituting (2.10) into (2.9) and simplifying

$$E(S^2) = \sigma^2(1 - 2\rho_1/n) \quad (2.11)$$

where

$$\rho_1 = -\theta/(1 + \theta^2) \quad (2.12)$$

It follows from (2.11) that S^2 will be overestimated for $\theta > 0$ and underestimated for $\theta < 0$. For large n , $E(S^2) = \sigma^2$.

3. EFFECT OF BIAS ON ARL OF CUSUM CHARTS

The use of cumulative sum control charts, as an alternative to standard control charts was introduced by Page [8]. Barnard [1] discussed their construction and use in quality control and introduced an elegant graphical procedure. By this method a V-shaped mask is superimposed on the cusum chart, the vertex pointing horizontally forwards and set at a distance d ahead of the most recent point. The angle between the obliques and the horizontal is denoted by θ . If all the previously plotted points fall within the V the process is assumed to be in control. Page [8] and Ewan and Kemp [4] discussed an equivalent numerical procedure by which cumulative sums are obtained on standardized deviations minus a reference value k . The effect of subtracting a reference value is to produce a downward slope of the cusums when the process is in control. An out-of-control signal is triggered as soon as this biased cusum graph exceeds its minimum by more than a specified amount h , called the decision interval. The relationship between the parameters d and θ of the test using the V-mask and the parameters k and h of the decision interval scheme is given by $h = wd \tan \theta$ and $k = w \tan \theta$ where w is the scale factor. Extensive tables for Average Run Lengths for various values of h and k are available for independent normal variates. (Ewan and Kemp [4], DeBruyn [3]). Goldsmith and Whitfield [5] gave an extensive set of graphs of the ARL as a function of the V-mask parameters d and θ using Monte Carlo methods. They also studied the effect of serial correlation among the observations on the ARL and provided two graphs showing ARL as a function of ϕ the serial correlation coefficient and δ , the displacement in the mean desired to be detected. Using their graphs an equivalent decision interval scheme with $h = 2.0$ and $k = 1.0$ can be

Table I. Bias as a function of ϕ, θ, n

ϕ	σ^2	$E(S^2)$			
		n=5	n=10	n=15	n=20
- .9	5.263	5.782 (9.9)	5.531 (5.1)	5.434 (3.2)	5.391 (2.4)
- .5	1.333	1.429 (7.2)	1.379 (3.5)	1.364 (2.3)	1.356 (1.7)
0	1.000	1.000 (0.0)	1.000 (0.0)	1.000 (0.0)	1.000 (0.0)
.5	1.333	1.129 (-15.3)	1.215 (-8.9)	1.251 (-6.2)	1.270 (-4.7)
.9	5.263	3.120 (-40.7)	3.428 (-34.9)	3.671 (-30.2)	3.865 (-26.6)
θ					
- .9	1.810	1.450 (-20.0)	1.630 (-10.0)	1.690 (-6.6)	1.720 (-5.0)
- .5	1.250	1.050 (-16.0)	1.150 (-8.0)	1.183 (-5.3)	1.200 (-4.0)
0	1.000	1.000 (0.0)	1.000 (0.0)	1.000 (0.0)	1.000 (0.0)
.5	1.250	1.450 (16.0)	1.350 (8.0)	1.317 (5.3)	1.300 (4.0)
.9	1.810	2.170 (20.0)	1.990 (10.0)	1.930 (6.6)	1.9 (5.0)

detected. Using their graphs an equivalent decision interval scheme with $h=2.0$ and $k=1.0$ can be derived for an AR(1) model (2.1) with corresponding ARL values for selected values of ϕ as given in Table II below. For high $\delta-k$ there is little dependence on the ARL on ϕ except when ϕ is close to 1. For low $\delta-k$ or higher ARL the effect is to decrease the ARL when ϕ is positive and to increase when ϕ is negative.

Table II. ARL as a function of ϕ , $h=2.0$, $k=1.0$

$\delta-k$	ϕ				
	.9	.5	0	-.5	-.9
-1.0	50.0	46.0	130.0	450.0	760.0
-0.5	36.0	23.0	49.0	125.0	290.0
0	23.0	6.0	9.0	12.5	30.0
1	6.1	3.1	3.0	2.7	2.7
2	2.0	1.6	1.6.0	1.6	1.6

Suppose the variance of the AR(1) process is estimated by using (1.1). Since standardized values are used in a decision interval scheme as discussed above, the effect of over and under estimation of the standard deviation is to multiply both cusum parameters effectively by that same factor. Using the percentage bias given in Table I for selected values of n modified values for h and k were obtained and ARL values

calculated individually for each combination of n and ϕ . For positive values of ϕ the effect of the bias was to reduce ARL while for negative values of ϕ the effect was to increase ARL with extreme variations when $|\phi|$ was close to 1 and when n is small. The effect of bias was more significant for positive values of ϕ compared to negative values of ϕ . In fact the effect of serial correlation and bias in estimation of the variance on ARL is minimal for moderate values of ϕ and n and in such cases existing tables for independent normal variates can be used for selecting cusum test parameters.

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LCS 114:20:400

DISCOVERY SAMPLING IN AN AUDIT SITUATION

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INTRODUCTION

A Quality Audit is defined as a systematic examination of the acts and/or decisions of people with respect to quality, verified by the examination of both methods and results. Therefore, it can be used to determine the suitability of a quality programme and/or the conformance to a quality programme.

Of necessity, the examination of methods and results must involve some form of sampling techniques. This application of sampling techniques differs somewhat from the normal sampling procedures, in that the auditor is not basically concerned with making an acceptance or rejection decision. In the audit situation, the auditor must be able to state that the operations do or do not conform to the quality programme or that the quality programme is or is not suitable.

PURPOSE

The purpose of a Quality Audit is to discover if any operational deficiencies are present and, if they are present, the extent of these deficiencies. This type of sampling called 'Discovery Sampling' in accounting circles has not received adequate attention in the quality audit field.

DISCOVERY SAMPLING

In Discovery Sampling, the basic factors that determine the sample size are:

1. The number of departures from the quality programme which are permitted,

and
2. The risk of failing to discover the departures.

The first factor to be determined is the number of departures from the programme which can be tolerated. This factor can vary from 0 to quite large numbers depending upon the nature of the Quality Audit. If the audit is covering a particularly critical function such as Inventory Control in a nuclear fuel facility, major safety or legal controls, then the number of departures which can be tolerated would be 0. In other areas having lesser system significance various numbers or percentages of departures could be tolerated.

The second factor to be determined is the risk of failing to include in the sample, examples of any departures present. This factor can be expressed either as the risk of failing to discover deficiencies, or alternatively, the confidence level that examples of the deficiencies have been discovered, if present.

In most Quality Audit situations confidence levels of 90% - 95% would normally be used. In extremely critical situations, such as those permitting no departures from the control programme, the confidence level would, of necessity, be much higher, e.g. 99% or greater.

SAMPLING PLANS - STANDARDS

Currently, no standards exist covering the sampling techniques in a Quality Audit situation. Some guidelines have been developed in the accounting circles. However, these do not have the recognition which would be given to a formally issued standard.

With the rapidly developing importance of the Quality Audit in many industries, I believe that the Standards Committee of the ASQC should undertake to develop and promulgate a Standard covering the various acceptable sampling plans used in an audit situation.

SAMPLING PLANS - REQUIREMENTS

A Society Standard on 'Discovery Sampling' would provide a foundation for a professional approach to Quality Audit. By the Society taking a lead in this important facet of the Quality Audit, the Society can demonstrate its concern with the Quality Audit.

In developing a standard there are two basic audit situations where sampling plans are required:

1. Those in which the population is known, with a fair degree of precision.
2. Those in which the population is not known, with any degree of precision.

In both situations, it will be necessary to have sampling plans which can relate:

1. The number of departures from the quality programme which are permitted.
2. The risk of failing to discover examples of these departures.

In developing the Sampling Plans, cognizance should be taken of the need to know the discrimination present in the Sampling Plan. Discrimination can be defined as the range of error rates lying between the upper and lower risk points for the sample size concerned. It, therefore, provides a measure of the band of error rates identified by the findings of the Quality Audit.

SAMPLING PLANS - IN PRACTICE

In practice, three approaches to Sampling Plans in a Quality Audit situation are commonly used:

1. Hypergeometric Sampling Plans applying in situations where the population is known, with a fair degree of precision.
2. Binomial Sampling Plans applying in situations where a limited number of departures from the control programme are permitted and the population is not known, with any degree of precision.
3. Lot Tolerance Percent Defective applying in those situations where a somewhat larger percentage of departures from the control conditions are permitted and the population is not known, with any degree of precision.

Various general Sampling Plans are in existence covering each of these three types of plans. However, their interpretation and application to audit situations will vary from auditor to auditor.

CONCLUSION

I believe that a Standard on recognized Sampling Plans for audit situations is required within the National Standards of both United States and Canada. With the ASQC involvement with the ANSI Z-1 Committee and its liaison activity with the Steering Committee on Assurance Sciences of the Canadian Standards Association, the Society is in a unique position to lead in the development of a Standard covering Sampling Plans for Quality Audits.

Some activity is currently underway on this topic in the Technical Committee on 'Application of Statistical Techniques' of the Canadian Standards Association. Currently, this work is directly involved with the audit of the Inventory Control on nuclear fuel. However, its activities will be broadened to cover the total audit situation.

LCS 345:10:000

ANOTHER LOOK AT L.Q. SAMPLING

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The purpose of this paper is to help those who must use sampling procedures and tables for Inspection by Attributes, contained in Mil-Std-105. This will also instruct them on some of the uses of Limiting Quality (LQ), for isolated lot, sample inspection, and to reduce overall inspection costs.

The purpose of inspection is to assure that the process is, or has, performed to the best of its capability. We look for rejects only when a process is known to be a producing defective product at a specific, lower than its capability, defect rate. Under normal inspection conditions, Sampling Procedures are used to reduce inspection errors: Bias; Fatigue; Monotony; Etcetera. Sampling tables are based on the laws of chance, (probability laws) and when used in accordance with these laws they will afford excellent protection against accepting a lot with a given percent defective, or rejecting a lot of Acceptable Quality Level (A.Q.L.).

Most organizations have adopted Mil-Std-105, "Sampling Procedures and Tables for Inspection by Attributes." Although this is the most widely accepted sampling procedure, or perhaps because of its wide acceptance, it is probably the most misused Military Standard.

As stated in the second paragraph, "The purpose of inspection is to assure that the process is, or has, performed to the best of ITS capability." In almost any process, from the simplest to the most complex, there is always a risk of producing a defective product. Quality Control and Inspection are charged with the responsibility of controlling that risk. The most economical method to control the risk is by Sample Inspection, performed correctly and accurately.

Why do we use sample inspection rather than 100% inspection of all products? The most obvious answer is: "Sample inspection takes less time and is therefore more economical." Second, suppose we were inspecting rifle shells with 100% inspection, we would end up with no product to ship. Finally it has been proven that even with 100% inspection, the Inspector will accept a portion of any defective material submitted for inspection, mainly due to Inspection error; Observation error; Bias; Manipulative error; Fatigue; Monotony; Boredom; Inadvertent error; and many others.

There are two general methods of inspection in use today, namely: Attribute and Variable inspection. Attribute inspection is primarily used to determine whether a characteristic exists, with respect to a given requirement, (Go and No-Go inspection), as an example in a push button switch, we inspect to assure that the contacts open or close to make or break an electrical circuit.

Attribute inspection is most often used in examination for visual defects, missing or existing operations and/or characteristics, workmanship defects, incorrect dimensions or other numerical values expressed as an accept or reject criteria (such as gaging with a pre-set, fixed gage). Attribute inspection is used to determine solely whether an item does or does not meet the established requirements without regards to actual numerical values.

The advantages of attribute inspection are many, among which some of the more important are: Cost, and Simplicity and Speed of inspection. The primary disadvantage is: Very little (if any) numerical value is known about the item under test, and therefore adjustments to the process are made on an intuitive basis. The amount of change required may not be fully known. In many cases this type of information is all that is required. That is, as an example: In punching operations, if an excessive burr exists, we may not need to know the exact dimension of the burr to know that the punch and/or die need re-work or sharpening.

Variable inspection is used to determine the precise point at which a characteristic measures. Example: Linear measurement of a length in thousandths of an inch, or the resistance of an electrical connection in Milli-Ohms. These may be converted to attribute inspection by using minimum and/or maximum values (limits) and disregarding any and all intermediate values. This is often performed by Go, No-Go gaging, such as thread ring and plug gages. We do not determine any numerical values, only conformance to the gage characteristics.

Items are usually submitted for inspection in one, or a combination of the following methods: Continuous production flow; or separated into lots and submitted as lot by lot, or isolated lot inspection.

Continuous production flow, is examination of items (usually 100%) as they are manufactured. This type of inspection is best suited for automatic inspection, such as sorting operations, either as good or bad, or into specific graduated measurement categories.

The most common inspection is lot by lot, either as completed, continuous, or partial lots. This is where common sense analysis is of prime importance. Procedures and tables must be used properly, to evaluate the approximate quality level of the item being inspected. The sampling procedures and acceptance level must be based upon proven statistical practices. The sample and rejection numbers must reflect the desired protection to both the producer and the consumer. Many of the lot by lot inspection plans should be calculated using "Isolated Lot Procedures." The term Isolated Lot actually refers to those sampling plans where the Limiting Quality (L.Q.) and consumers risk are applied. The lots do not have to be isolated in the physical sense before applying these plans to the concepts of sampling inspection procedures. Limiting Quality is "The Worst Quality Level that you are willing to accept a portion of the time." This may seem to be a rather harsh statement, such as: "I am willing to accept 4% defective, 5% of the time." What I have actually said is: "If the process is producing at an average of 4% defective, I am willing to accept only one (1) lot of twenty (20) lots submitted. The remaining nineteen (19) lots will be rejected, depending on the process average remaining at 4% defective. If the process average changes all various percent defective lots will have a pre-determined chance of acceptance. This chance may easily be determined by using the tables and data found in Mil-Std-105.

With Limiting Quality Inspection, lot by lot sampling, the average outgoing Quality Limit (A.O.Q.L.) may be determined from the A.Q.L. of the sampling plan. In our example of L.Q. of 4% defective 5% of the time. We arrive at an A.Q.L. of 0.65 (using a sample size of 200 pieces). The A.O.Q.L. for this plan, from table V of Mil-Std-105 is 0.97. Note: For the exact A.O.Q.L. this factor must be multiplied by;

$$\frac{\text{Sample Size}}{(1 - \text{Lot Size})}$$

If we assume the lot size to be 5,000 pieces, the exact A.O.Q.L. is $0.9312 (1 - \frac{200}{5,000}) \times 0.97 = 0.9312$. If our lot size is 10,000 pieces the A.O.Q.L. is $0.97 \times (1 - \frac{200}{10,000}) = 0.9506$. This is assuming all defectives from the rejected lots are removed and replaced with acceptable product.

Let's take a closer look at L.Q. type of Acceptance Sampling. First off, Limiting Quality (L.Q.) is defined (per Mil-Hdbk-53) as "The Worst Product Quality that the consumer is willing to accept." I believe this has lead most of us to believe large sample sizes and therefore high inspection costs. This, as I will try to prove, may not always be true.

Sampling plans may be devised to provide a specific Limiting Quality protection to the consumer. These plans should be used with "Isolated Lot" (one time or intermittent production) where very little or No control is made over the process. Plans of this type are designed primarily to provide protection to the consumer.

I will explain a simple plan that can give equal or better consumer protection for a 2.5% A.Q.L. if our average sample size has been 200 pieces. With this plan we accept with 10 rejects and reject on 11 defects. About 5% of the time we may accept a lot as bad as 8.48% defective.

Now if I consider this to be acceptable, I can state that "I am willing to accept 8.5% defective 5% of the time. I can now go to table VII-A of Mil-Std-105 and choose a plan or plans which will give me this protection. There are, in fact, four (4) plans which give this approximate protection: These I have listed below:

SAMPLE SIZE	REJECTION NUMBER	(Pa) PROTECTION
32	1	8.9%
80	3	7.7%
125	6	8.4%
200	11	8.5%

Any of these will give the stated protection as shown: At a 5% level. I am now suggesting a double or triple sampling plan using the above listed sample sizes and rejection numbers.

The procedure would be as follows: An initial sample of 80 pieces shall be drawn from each lot and examined for conformance to specifications. If two (2) or less defectives are found, the lot shall be accepted. If three to five (3 to 5) defects are found (of the same characteristic) an additional forty-five (45) pieces shall be drawn for a full sample of 125 pieces. If a total of five (5) or less defectives are found in the full sample of 125 pieces, the lot shall be accepted. If six (6) or more defectives are found, the lot shall be rejected, (by the inspector).

Sampling plan for Limiting Quality Protection of 8.5% defective at a 5% consumer risk:

PLAN:	Initial Sample	80 Pieces
	Defectives:	Disposition:
	0 - 2	Accept the lot
	3 - 5	Draw full sample
	6 - Over	Reject the lot
	Full Sample	125 Pieces
	Defectives:	Disposition:
	0 - 5	Accept the lot
	6 - Over	Reject the lot

This sample plan uses an initial sample of 80 pieces, and a full sample of 125 pieces. This plan may be used regardless of lot or batch size, with the following conditions applied: 1) The sample must be drawn as randomly as possible; 2) Each lot or container of over 3,000 pieces shall be subjected to examination, each container must have its own sample drawn and inspected per the sampling plan criteria as follows:

CONTAINERS IN LOT:	CONTAINERS TO BE SAMPLES:
2 - 15	2
16 - 25	3
26 - 90	5

If any of the sample containers contains more than six (6) defectives, all containers shall be subject to sample inspection, at the discretion of the responsible party and/or parties. 3) When a lot of items is submitted in more than one container and the total of all containers is less than 3,000 pieces, the containers may be combined to fulfill the 3,000 piece requirement, but must not exceed 6,000 pieces, for the combined total of all containers in the lot.

You may want to use one of the other plans such as: 32 pieces in the initial sample and 80 pieces for the full sample. This could be used for reduced inspection, for known good vendors. You may want to use 125 piece initial sample and 200 piece full sample for tightened for vendors of doubtful quality. In any case the choice is yours and you may reduce inspection costs without giving up your desired protection.

With Limiting Quality (L.Q.) plans the reduction in inspection costs can be significant and your protection may be increased. With L.Q. plans your good vendors will be rewarded and your poor vendors will be more easily identified, at less cost.

I would definitely recommend a dual or multiple sample plan using Limiting Quality. From my own experience I have found we have inspected about 33% more lots with the same number of inspectors, and have had no adverse effect on our Quality for the past six months. This has resulted in a cost reduction of about 25% in our receiving inspection department.

In all inspection there are certain risks inherent with inspection. In sample inspection there is the additional risk of human performance. A special risk attributed to bias and "Luck of the Draw." These may result in false decisions, relative to "Good" and "Bad" lots. In sampling inspection there is always a chance, or risk, that good lots may be rejected, or bad lots accepted. Generally, the smaller the sample size the greater the risk. Since risks are inherent, to all inspection, and more so to sample inspection these risks must be clearly understood by all who use sampling plans and procedures. These risks may be explained as follows: Assuming a lot of items, with a given percent defective is submitted for inspection, at the inspection station: What are the odds of accepting or rejecting the lot? This may be determined by the tables, data, and Operating Characteristic curves given in Tables X of Mil-Std-105.

Due to the variations of the sample (human performance) the sample results may lead to incorrect acceptance or rejection of any given lot. That is; a sampling plan may result in a small percentage of good lots being rejected, this is referred to as the suppliers or "Alpha" risk; and likewise, the sampling plan may accept a small percentage of bad lots, this is referred to as the consumers risk or "Beta" risk: These are afore-mentioned and are predictable by the tables and graphs in Mil-Std-105. If you desire to calculate some specific risk, not given in Mil-Std-105, these may be calculated using the terms of Poisson's exponential binomial limits. You may use interpolation of the Mil-Std-105 tables, for a close approximation.

Conclusion and Summary: Quality Control is charged with the responsibility of reducing overall cost and in the Electro-mechanical business our biggest cost is Inspection. If we can reduce this cost and still "Assure that the process is, or has, performed to the best of its capability", we shall have made a significant contribution to our organization.

The appendix is taken from Mil-Std-105, and is shown here to aid in the use of these tables.

Table VII A shows 4 sampling plans which may be used for a 8.5% consumers risk at the 5% level. These plans correspond with A.Q.L.'s as shown. For example: A sample size of 32 pieces corresponds to a 0.40 acceptable quality level and a sample size of 200 pieces corresponds to a 2.5 A.Q.L.

Table II A shows the rejection number associated with each plan.

Table V A shows the average out-going quality limit associated with each plan.

TABLE VII-A—Limiting Quality (in percent defective) for which $P_a = 5$ Percent
(for Normal Inspection, Single sampling)

Code letter	Sample size	Acceptable Quality Level													
		0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0
A	2														
B	3														
C	5													45	63
D	8												31		
E	13											21			32
F	20										14			22	28
G	32									8.9			14	18	23
H	50											9.1	12	15	26
J	80							3.7			5.8	7.7	9.4	13	16
K	125						2.4			3.8		6.2	8.4	11	14
L	200								2.4	3.2	3.9	5.3	6.6	8.5	11
M	315				0.95	1.5		1.5	2.0	2.5	3.3	4.2	5.4	7.0	9.6

TABLE II-A—Single sampling plans for normal inspection (Master table)

[illegible]

TABLE V-A—Average Outgoing Quality Limit Factors for Normal Inspection (Single sampling)

[illegible]

Notes: For the exact AOQL, the above values must be multiplied by $(1 - \frac{\text{Sample size}}{\text{Lot or Batch size}})$

SUPPLIER AWARD OF EXCELLENCE

A SUCCESSFUL PROGRAM

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ABSTRACT

The Xerox Supplier Award of Excellence Program was initiated in 1970 to recognize and honor suppliers with outstanding quality performance. The original supplier selection criteria was based strictly on quality performance as measured by Receiving Inspection records. The current program, changed in 1973, is based on such factors as delivery, technical competence, cost consciousness and service, in addition to quality performance. These additional measures of performance upgrade the original quality award to a more comprehensive award of performance excellence. This paper describes the characteristics of the program which have made it a successful management tool at Xerox.

INTRODUCTION

April can rightfully be called Supplier Recognition Month at Xerox Corporation. Since 1970, Xerox has been recognizing its top suppliers in April with a formal award. This year was no exception. Xerox presented its Award of Excellence to 66 of its top suppliers for the outstanding work they did for the company in 1976. For 26 of those companies, this was the second consecutive year they earned the coveted award. One company has received the award each year since its inception.

Fewer than one percent of the corporation's suppliers qualify for the annual award which is based on such factors as quality, delivery, technical competence, cost consciousness and service. The suppliers are selected by an awards selection committee which is made up of two members from Supplier Quality Assurance and five members from Materials Management. A chairman is selected each year by Materials Management.

MEASURE OF SUCCESS

The success of any program of this type is difficult to measure. However, the supplier repeat rate is considered a good measure of success. From the 1976 awards, the following is the award scorecard:

First time winners	-	45%
Second time winners	-	38
Third time winners	-	10
Fourth time winners	-	5
Fifth time winners	-	2

Sixty-five percent of the suppliers who received the award in 1976 were repeat performers. This level of repeat performance is an indication of how successful the program is at Xerox

SELECTION PROCESS

The selection process begins by the end of December when Supplier Quality Assurance selects the top 200 suppliers who have delivered at least thirty (30) lots during the year and have achieved a 90% or better quality record. In addition, the supplier must be an S.Q.A. Survey Approved supplier. From this list, Materials Management (Procurement) eliminates those suppliers with poor delivery records. The resultant list is then submitted to each Procurement Sub-section manager for the final list. Procurement and Supplier Quality Assurance are then each allowed a very limited number of "wild card" choices. Such choices must be documented and justified and they are subject to review and approval by the selection committee.

NOTIFICATION

When a supplier is finally chosen, Procurement notifies him by mail. This is usually done early in the month that the award is presented. The letter of notification informs the supplier that he has been selected for the award, and it invites the supplier to attend and identify who will be present at the Awards Banquet to receive the award. Each supplier usually brings two to three people.

AWARDS BANQUET

The Awards Banquet is normally held at a hotel in Rochester, New York. Xerox Procurement and Supplier Quality Assurance divide the cost of the dinners, refreshments, table arrangements, other hotel related costs, the cost of the awards presented to the supplier and the plaque for Xerox listing the names of all suppliers who received the award. The supplier is expected to pay for his travel, room and meals other than the Banquet. In 1976, these costs were less than ten thousand dollars (\$10,000).

OTHER FACTORS

There are no restrictions on how suppliers may use the Xerox award "internally", that is, within their own company newspapers or other vehicles of communication. However, there is a Xerox policy which requires award winners to obtain prior Xerox approval to use the award in any public news release.

TESTIMONIALS

This is not the place to identify and quote specific testimonials, but it is important to make some general comments from the testimonials received from award winners. Their general theme is that (1) they are pleased to have been recognized to receive the award, (2) they are proud to display the award, (3) they feel that the award reflects a high level of quality standards, and (4) the award motivates them to maintain a high level of performance standards.

CONCLUSION

We at Xerox believe that the Supplier Award of Excellence Program works. That is, it recognizes those suppliers that meet objectives, it motivates suppliers to maintain a high level of performance over time, and it brings quality, cost and delivery oriented people closer together to improve upon previous years performance.

LCS 300:40:436

COMPUTER DESIGN OF OPTIMUM VARIABLE SAMPLING PLANS

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ABSTRACT

The University of Dayton, School of Engineering, has developed a series of interactive computer programs that solve most of the traditional and many special quality control problems. This paper shows practical applications for eight of these programs (SL.F.DEF, SL.2P.OC, SL.OC.5, DL.2P.FD, SU.2P.OC, DU.2P.FD, SXB.OC, and DXB.OC), all associated with variable sampling plans. Since each program is written in FORTRAN IV and is as computer-independent as possible, each is easily compilable on most companies' computers. Further, since all programs are interactive, they may be used by any quality control person who has access to a teletype terminal.

The paper discusses how to design and evaluate variable sampling plans for special conditions not covered in standard sampling schemes such as MIL-STD-414. Actual examples are given, showing step-by-step procedures to design and/or evaluate sampling plans that meet defined producer and consumer risks for both fraction defective and \bar{X} plans for either single or double specification limits and with or without known sigmas.

INTRODUCTION

This paper discusses eight interactive computer programs, all related to acceptance sampling by variables. These programs are divided into three groups: (1) plans similar to MIL-STD-414, Section D, to control fraction defective where sigma is known (SL.2P.OC, DL.2P.FD, and SL.OC.5); (2) plans similar to MIL-STD-414, Section B, to control fraction defective where sigma is unknown (SU.2P.OC and DU.2P.FD); and (3) plans to give assurance regarding the mean of a process or lot (SXB.OC and DXB.OC). One additional program, "Single Limit Fraction Defective" (SL.F.DEF), is included to define and illustrate the effect of changes in \bar{X} and σ on the fraction defective of a process controlled by a single limit (either lower or upper) specification. This latter program is primarily descriptive and useful in simulating conditions in industry to aid management made decisions concerning changes in processes. Further, the printouts from it provide a convenient means to introduce the subject of acceptance sampling by variables; therefore, it will be discussed first.

Normally Distributed Quality Characteristics

In almost all cases, available variable sampling plans assume that the quality characteristic being inspected is normally distributed in the underlying population (i.e., the lot or process being sampled). This assumption is usually close enough to the actual condition so that variable sampling plans based on it are useful in analyzing quality in real-world situations. All of the computer programs discussed in this paper use this assumption of normality, although one program (DU.2P.FD) does use the "t" distribution to compensate for small sample size.

The program "SL.F.DEF" assumes that the quality characteristic of interest is normally distributed and that approximations of \bar{X} and σ can be selected that are reasonable and useful in analyzing the real-world process in which we are interested. The capabilities and value of this program are best illustrated by example.

PROGRAM "SINGLE LIMIT FRACTION DEFECTIVE" (SL.F.DEF)

Consider first a problem of process control at a dairy. One of the products packaged by this dairy is milk with a guaranteed minimum of 2 percent butterfat. Government regulation states that not more than 2-1/2 percent of the lots selected at random and tested may be less than 2 percent butterfat. Program SL.F.DEF requires dimensional quantities as input; therefore, it is necessary to convert the lower limit value of 2 percent butterfat to a dimensional value such as ounces per quart. This is easily done as follows:

$$(0.02)(32) = 0.64 \text{ oz/qt.}$$

Let us assume that prior experience has shown that when processing small batches the average butterfat content needs to average 0.80 oz/qt or more, if almost all batches are to test out at 0.64 oz/qt or above. This average excess of 0.16 oz/qt of butterfat

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is expensive, and it has been suggested that the variation between lots could be reduced if the milk were handled in larger lots and more thoroughly blended.

Computer input and output of program SL.F.DEF for this problem are shown in Figure 1. Convenient ranges in oz/qt were selected for \bar{X} (0.72 to 0.80) and for σ (0.04 to 0.08). As a study of Figure 1 shows, the computer program is interactive and asks the operator a series of questions which leads to an understandable printout for the process in question.

```
EXEC SL.F.DEF
% P500 000,SLFD.
FIRTRAN IV PROGRAM SLFD   STARTED --- 12/23/77

PLEASE POST A TITLE FOR THE STUDY (40 CHARACTERS OR LESS).
* BUTTERFAT IN 2% MILK
PLEASE POST THE DIMENSIONS OF THE STUDY (40 CHARACTERS OR LESS).
* DUNCES BUTTERFAT PER QUART (OZ/QT)
WHICH SINGLE SPECIFICATION LIMIT UPPER OR LOWER (U,L) ?
*L
PLEASE INPUT THE LOWER SPECIFICATION LIMIT
* 0.640
PLEASE INPUT 5 VALUES OF SIGMA SEPARATED BY COMMAS
* .04,.05,.06,.07,.08
PLEASE INPUT 5 VALUES OF XBAR SEPARATED BY COMMAS
* .72,.74,.76,.78,.80
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER? (Y,N)
* N

*****
* TITLE: BUTTERFAT IN 2% MILK
* DIMENSIONS: DUNCES BUTTERFAT PER QUART (OZ/QT)
* RELATIONSHIP BETWEEN THE MEAN AND STANDARD DEVIATION OF A
* NORMALLY DISTRIBUTED PROCESS OR LOT AND ITS FRACTION DEFECTIVE
*****
* LOWER SPECIFICATION LIMIT = 0.640
*****
* SIGMA VALUES
* XBAR * 0.040 0.050 0.060 0.070 0.080
* VALUES *****
* FRACTION DEFECTIVE
* 0.720 * 0.02275 0.05480 0.09121 0.12655 0.15866
* 0.740 * 0.00621 0.02275 0.04779 0.07656 0.10565
* 0.760 * 0.00135 0.00820 0.02275 0.04324 0.06681
* 0.780 * 0.00023 0.00236 0.00982 0.02275 0.04006
* 0.800 * 0.00003 0.00069 0.00383 0.01114 0.02275
*****
* (3) (5) (2) (1) (4)
```

FIGURE 1 -- Input and output of program SL.F.DEF for a process with lower specification limit.

Figure 2 was prepared as an aid in explaining the significance of two values (0.02275 and 0.10565) in Figure 1 [note items (1) and (2)]. The "fraction defective" section of Figure 1 as well as the location of critical points on Figures 2, 3, and 4 were developed using the "area under the tail" from a standard normal distribution area versus "z" table. The calculations are included as a subroutine within program SL.F.DEF. For example, the standard z value for item (2) in Figure 1 was calculated as shown in Equation (1).

$$z = (X_1 - \bar{X})/\sigma = (0.64 - 0.74)/0.08 = -1.25. \quad (1)$$

For a z value of -1.25, a standard normal distribution table shows the area under the left tail to be 0.10565.

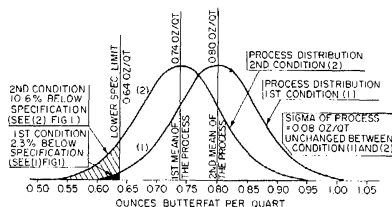


FIGURE 2 -- Increase in percent defective by decreasing the mean (\bar{X}) of a process with lower specification limit.

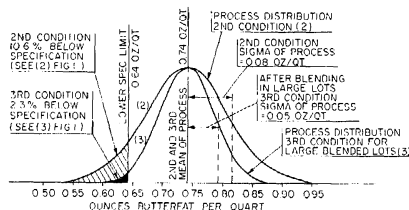


FIGURE 3 -- Decrease in percent defective by reducing the variation (σ) of a process.

Item (1) in Figure 1 (i.e., 0.02275) and the corresponding value (2.3 percent) at the left tail of the distribution of process (1) in Figure 2 illustrates the operating conditions assumed above for the milk processing plant ($\bar{X} = 0.80$, $\sigma = 0.08$).

If the dairy were to reduce the average quantity of butterfat (\bar{X}) from 0.80 to 0.74 oz/qt without doing anything to reduce the variation in the process ($\sigma = 0.08$), then 10.6 percent of the lots would test out as being below the lower limit of 0.64 oz/qt of butterfat [note item (2) in Figures 1 and 2].

It should be possible to reduce variation in the butterfat content of the milk by processing it in larger lots and blending it more thoroughly. For example, if σ were reduced from 0.08 to 0.05 oz/qt, then the average quantity of butterfat (\bar{X}) could be reduced from 0.80 to 0.74 oz/qt, without increasing the number of rejected lots above the 2-1/2 percent regulation. This condition is illustrated as item (3) in Figure 1 and distribution (3) in Figure 3.

In most real-world situations, it is not possible to economically reduce the variation of a process to accomplish the desired results as illustrated above between items (1) and (3) in Figure 1 and between distribution (1) in Figure 2 and distribution (3) in Figure 3.

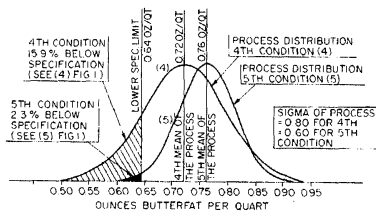


FIGURE 4 -- Decrease in percent defective by both increasing the mean and decreasing the variation of a process with lower specification limit.

In most cases a compromise is necessary. In this case such a compromise might be to reduce the variation of the process somewhat and at the same time use a tradeoff of allowing a higher average \bar{X} . This compromise is illustrated as items (4) and (5) in Figure 1 and distributions (4) and (5) in Figure 4. Here the change between condition (4) and (5) illustrates both a change of \bar{X} from 0.72 to 0.76 and a change of σ from 0.08 to 0.06. This simultaneous increase of \bar{X} and decrease of σ results in a reduction of the lots below the lower limit from 15.9 to 2.3 percent. This is typical of real-world compromises that are necessary to bring a process into control.

As can be seen from Figure 1 and the explanation of this figure in Figures 2, 3, and 4, the program SL.F.DEF can be used to simulate conditions in a real-world process. It is possible using the printout of program SL.F.DEF to forecast the effect of changes in \bar{X} and σ on the fraction defective of a process in question (i.e., the percent of the lots with an \bar{X} below the lower limit).

Program SL.F.DEF can also be used for processes that have a single upper limit. This use of the program is illustrated by Figures 5 and 6. These two figures show a

```
EXEC SL.F.DEF
% P500 000,SLFD.
FORTRAN IV PROGRAM SLFD   STARTED --- 12/23/77

PLEASE POST A TITLE FOR THE STUDY (40 CHARACTERS OR LESS).
*PERCENT MOISTURE IN SCOURING POWDER
PLEASE POST THE DIMENSIONS OF THE STUDY (40 CHARACTERS OR LESS).
*GRAMS MOISTURE PER KILOGRAM (G/KG)
WHICH SINGLE SPECIFICATION LIMIT UPPER OR LOWER (U,L) ?
*U
PLEASE INPUT THE UPPER SPECIFICATION LIMIT
*15
PLEASE INPUT 5 VALUES OF SIGMA SEPARATED BY COMMAS
*.125,.150,.175,.200,.225
PLEASE INPUT 5 VALUES FOR XBAR SEPARATED BY COMMAS
*14.5,14.6,14.7,14.8,14.9
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER? (Y,N)
*Y
*****
* TITLE: PERCENT MOISTURE IN SCOURING POWDER
* DIMENSIONS: GRAMS MOISTURE PER KILOGRAM (G/KG)
*****
* RELATIONSHIP BETWEEN THE MEAN AND STANDARD DEVIATION OF A
* NORMALLY DISTRIBUTED PROCESS OR LOT AND ITS FRACTION DEFECTIVE
*****
* UPPER SPECIFICATION LIMIT = 15.000
*****
* SIGMA VALUES
* XBAR VALUES
*****
* FRACTION DEFECTIVE
*****
* 14.500 * 0.00003 0.00043 0.00214 0.00621 0.01313
* 14.600 * 0.00069 0.00383 0.01114 0.02275 0.03772
* 14.700 * 0.00820 0.02275 0.04324 0.06681 0.09121
* 14.800 * 0.05480 0.09121 0.12655 0.15865 0.18703
* 14.900 * 0.21185 0.25249 0.28365 0.30854 0.32836
*****
(2) (1)
```

FIGURE 5 -- Input and output of program SL.F.DEF for a process with upper specification limit.

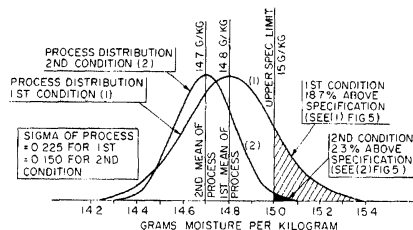


FIGURE 6 -- Decrease in percent defective by both reducing the mean and decreasing the variation of a process with upper specification limit.

process where the moisture content should not exceed a certain level, otherwise, the product becomes inferior. In the example case, scouring powder with more than 1.5 percent moisture tends to cake and if packaged and shipped would seriously affect consumer acceptance. Using dimensioned values as discussed above and the metric system, the upper specification limit could be defined as:

$$(0.015)(1000) = 15 \text{ grams moisture per kilogram (15g/kg)}.$$

With this value as the base, realistic values for \bar{X} and σ were entered into program SL.F.DEF with Figure 5 as the results. The change between item (1) and item (2) in Figure 5 and between the distributions (1) and (2) in Figure 6 illustrate the effect of simultaneously changing \bar{X} from 14.8 to 14.7 and σ from 0.225 to 0.150 g/kg. The net effect of this reduction of both \bar{X} and σ would assure that the percentage of lots with a moisture content above the specification limit would be reduced from 18.7 to 2.3 percent.

DESIGN AND EVALUATION OF SINGLE LIMIT VARIABLE SAMPLING PLANS

Operating Characteristics (OC) Curves

An operating characteristic (OC) curve provides the means of evaluating the operation of all types of acceptance sampling plans including the variable sampling plans discussed in this paper. An OC curve depicts varying conditions of incoming materials and illustrates the risks inherent in a sampling plan at each quality level of incoming material. In this sense an OC curve is a means of defining the actual characteristics of a given acceptance sampling plan. Thus, every possible acceptance sampling plan has an OC curve, whether or not such a curve has ever been calculated or plotted.

In most cases it is possible to design a variable sampling plan in terms of two values of fraction defective, which, in turn, can be easily located on the OC curve. As will be explained later, these two values are usually located in lines 4 and 21 in the tabulated values of OC curves printed by the computer programs.

At the lower fraction defective value (normally called p'_1) the producer is willing to take a risk (α) of rejecting a lot of this quality or higher. At the higher fraction defective value (normally called p'_2) the consumer is willing to take a risk (β) of accepting a lot of this quality or lower. These two risks and the fraction defective associated with them can be defined as follows.

Producer's Risk (α) is the risk of rejecting a lot of very high quality, i.e., a lot having a very low fraction defective. This is usually defined as the probability ($1-\alpha$) of accepting a lot of quality p'_1 or less [often referred to as Acceptable Quality Level (AQL)].

Consumer's Risk (β) is the risk of accepting a lot of very poor quality, i.e., a lot of very poor quality, i.e., a lot having a very high fraction defective. This is usually defined as the probability (β) of accepting a lot of quality p'_2 or more [often referred to as Limiting Quality (LQ); occasionally called Lot Tolerance Percent Defective (LTPD)].

Comparisons to MIL-STD-414

In the balance of this paper comparisons will be made between optimum sampling plans designed by computer programs and plans included in the MIL-STD-414 sampling scheme. First, there could be confusion in the meaning of the term "Acceptable Quality Level." This is defined in Section A4.1 of MIL-STD-414¹ as "a nominal value expressed in terms of percent defective specified for a single quality characteristic." This definition does not refer to producer's risk nor the many different actual values of p'_1 applicable to the various sampling plans contained within MIL-STD-414.

In order to be consistent with theoretical concepts, the terms AQL and p'_1 will be used interchangeably in this paper. In MIL-STD-414 and other Government standards, AQL is expressed as percent defective. In this paper, as in most technical publications, p'_1 is expressed as fraction defective, i.e., the decimal point is moved two places left. Further, in order to simplify discussions the value 0.05 will always be used for α , the producer's risk, and the value 0.10 will always be used for β , the consumer's risk.

COMPUTER DESIGN OPTIMUM VARIABLE SAMPLING PLANS

MIL-STD-414 states in Section A6.2² "Sampling plans and procedures are provided in Section B if variability is unknown and the standard deviation method is used, in Section C if variability is unknown and the range method is used, and in Section D if variability is unknown. Unless otherwise specified, unknown variability, standard deviation method sampling plans, and the acceptability criterion of Form 2 (for the single specification limit case) shall be used."

It is convenient to discuss program "Single Limit, Two Point, OC" (SL.2P.OC) first in connection with designing optimum variable sampling plans. This program designs plans similar to Form 1 plans in Section D of MIL-STD-414, i.e., plans where variability is known. This situation of known variability is often found in industry since the variability of a machine or process usually changes only slightly from time to time, whereas machine or process settings (which affect the mean of the process, \bar{X}) may differ on occasions.

It is important to note that in this paper the emphasis is on the design of optimum variable sampling plans--not the design of forms to facilitate the use of these plans. When using procedures outlined in MIL-STD-414, a value of "k" is determined when Form 1 is used and a value of "M" is determined when Form 2 is used. These two forms are equivalent since both arrive at the same accept or reject decision. Further, "M" represents the area under the tail of the normal distribution "k" standard deviations from the mean of the sample. This area may be obtained easily when applying any of the four computer programs: SL.2P.OC, DL.2P.FD, SU.2P.OC, and DU.2P.FD. Each of these four plans calculate "n" and "k" and then define a sampling plan for inspection by variables in a manner analogous to MIL-STD-414, Form 1.

A Typical Variable Sampling Plan from MIL-STD-414

Consider as an example a certain steel casting that has a specified minimum yield point of 68,000 psi and comes from a process with a known variation of $\sigma = 950$ psi. A lot of 600 items is submitted for inspection. If it has been agreed to use inspection level IV, normal inspection and an AQL of 0.65 percent, one would refer to Tables A-2 and D-1 of MIL-STD-414 where it can be seen that size code J is to be used. With size code J and an AQL of 0.65 percent, Table D-1 calls for a sample size (N) of 10 and an acceptability constant (k) of 1.99. Figure 7 was taken from MIL-STD-414 and shows the OC curve for size code J with an AQL of 0.65 percent. Interpolating from this curve shows that at a producer's risk (α) of 0.05, p_1' is 0.0060 instead of 0.0065 that would be expected with a specified AQL of 0.65 percent. Further, at a consumer's risk (β) of 0.10, the curve indicates that p_2' (or LQ) would be 0.0566.

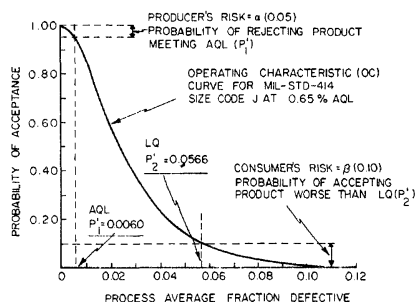


FIGURE 7 -- Operating characteristic (OC) curve for a typical variable sampling plan (Code "J", AQL = 0.65%) from MIL-STD-414.

PROGRAM "SINGLE LIMIT, TWO POINT, QC" (SL.2P.OC)

The name of this program and others to be discussed in this paper, is descriptive of its input and output. In this case the program designs a single limit (either lower or upper) variable sampling plan by inputting the X and Y coordinates from two points on the OC curve. These two points are always p_1' at α and p_2' at β . The output of the program is the specifications of a sampling plan with sample size, n, and acceptability constant, k, together with a tabulation and plot of the OC curve. Figure 8 shows both the input and output of the computer program SL.2P.OC for a plan very similar to the one called for by MIL-STD-414 for the conditions outlined above in connection with Figure 7. The difference is that p_1' was specified as 0.0065 instead of the 0.0060 obtained by using size code J and an AQL of 0.65 percent from MIL-STD-414. Further, the consumer's risk was rounded to 0.0600 instead of the 0.0566 that resulted from MIL-STD-414. The printout in Figure 8 gives the plan in terms of the lower specification limit, the known σ , n, and k. These latter two values were calculated within the program by a rather complex but well-documented algorithm that is well explained by Duncan.⁵ Computer program SL.2P.OC is written such that a single upper limit plan may be designed as well as a single lower limit plan (e.g., Figure 8). All that is

```

/EXEC SL.2P.OC
* P500 LOADING VEP# 000 OF SL2P.OC.
FORTRAN IV PROGRAM SL2P.OC STARTED --- 01/09/78

DO YOU HAVE A VALUE FOR N AND K? (Y,N)
*N
PLEASE POST P'1 AS A FRACTION DEFECTIVE (ACL- "ACCEPTABLE QUALITY
LEVEL" AT THE PRODUCER'S RISK LEVEL OF PROBABILITY OF REJECTION)
*.0065
PLEASE POST P'2 AS A FRACTION DEFECTIVE (LC- "LIMITING QUALITY"
AT THE CONSUMER'S RISK LEVEL OF PROBABILITY OF ACCEPTANCE)
*.06
PLEASE POST ALPHA (PRODUCER'S RISK)
*.05
PLEASE POST BETA (CONSUMER'S RISK)
*.10
IS THIS A SINGLE UPPER LIMIT OR A SINGLE LOWER LIMIT PLAN (U,L)
*L
WHAT IS THE LOWER LIMIT
*68000
WHAT IS THE KNOWN SIGMA OF THE PROCESS?
*950
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER? (Y,N)
*N

```

```

*****
* FRACTION DEFECTIVE VARIABLE *
* SAMPLING PLAN WITH SINGLE *
* SPECIFICATION LIMIT *
*****
* KNOWN SIGMA AND BASED ON *
* NORMAL DISTRIBUTION *
*****
* LOWER SPECIFICATION LIMIT= 68000.00 *
* SIGMA= 950.00 *
* P'1= 0.0065 ALPHA= 0.0500 *
* P'2= 0.0600 BETA= 0.1000 *
* N= 10 K= 1.9618 *
*****
* PLAN: *
* STEP 1: DRAW A RANDOM SAMPLE OF 10 *
* STEP 2: CALCULATE X.BAR *
* STEP 3: ACCEPT IF *
* (X.BAR- 68000.00)/ 950.00 >= 1.9618 *
* OTHERWISE REJECT *
*****
* PROB. *
* FRACTION DEFECTIVE *
*****
* 0.999 0.0016 *
* 0.995 0.0027 *
* 0.990 0.0035 *
* 0.950 0.0065 *
* 0.900 0.0090 *
* 0.850 0.0110 *
* 0.800 0.0129 *
* 0.750 0.0148 *
* 0.700 0.0167 *
* 0.650 0.0186 *
* 0.600 0.0206 *
* 0.550 0.0227 *
* 0.500 0.0249 *
* 0.450 0.0273 *
* 0.400 0.0299 *
* 0.350 0.0329 *
* 0.300 0.0362 *
* 0.250 0.0402 *
* 0.200 0.0450 *
* 0.150 0.0511 *
* 0.100 0.0598 *
* 0.050 0.0747 *
* 0.010 0.1101 *
*****

```

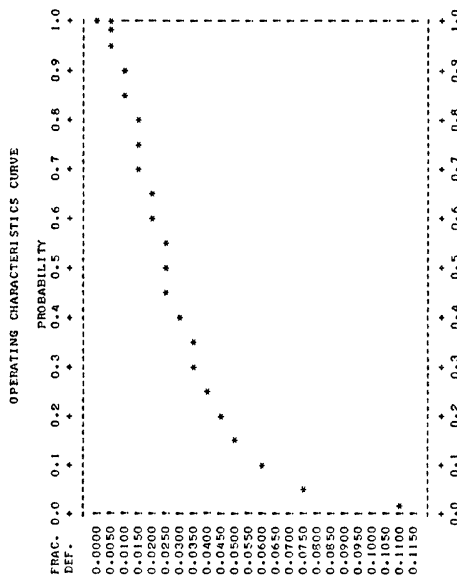


FIGURE 8--Input and output of program SL.2P.OC for the design of a lower limit variable sampling plan with $L = 68000$, $\sigma = 950$, $p'_1 = .0065$, $p'_2 = 0.06$, $\alpha = 0.05$, $\beta = 0.10$.

required is to input "U" instead of "L" when the computer asks "Is this a single upper limit or a single lower limit plan (U,L)."

EVALUATION OF SINGLE LIMIT VARIABLE SAMPLING PLANS

Since OC curves provide a means of evaluating the operation of acceptance sampling plans, a computer program (SL.OC.5) was developed to compare the operating characteristics of up to five single limit variable sampling plans. Figure 9 is an example of the input and output of this program. Plan 1 represents the MIL-STD-414 plan for size code J with an AQL of 0.65 percent as shown in Figure 7. Plan 2 is a repeat of the OC curve in Figure 8.

The algorithm used in program SL.2P.OC (see Figure 8) gives a very good approximation of the optimum single limit variable sampling plan that meets the input criteria of p'_1 at α and p'_2 at β . As can be seen in Figure 8 and column 2 of Figure 9, the plan $n = 10$ and $k = 1.9618$ meet the p'_1 (line 4) criteria but is slightly low for p'_2 (0.0599 instead of the desired 0.0600) in line 21. It is often possible, by using program SL.OC.5 with various values for k , to meet input criteria exactly. Column 3

```

HOW MANY SAMPLING PLANS DO YOU WISH TO ANALYZE?
*5
INPUT THE SAMPLE SIZE FOR EACH
OF THE SAMPLING PLANS SEPARATED BY COMMAS
*10,10,10,5,6
INPUT THE ACCEPTANCE CRITERION (K) FOR EACH
OF THE SAMPLING PLANS SEPARATED BY COMMAS
*1.990,1.962,1.961,1.880,1.805
DO YOU WISH TO TRUNCATE THE PLOT? (Y,N)
*N
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER?
*N
*****
* OPERATING CHARACTERISTICS CURVES
* FOR PLANS WITH A SINGLE SPECIFICATION LIMIT
*****
* PLAN
* SAMPLE SIZE      10      10      10      5      6
* VALUE OF K      1.990    1.962    1.961    1.880    1.805
*****
POINT  P(A)      FRACTION DEFECTIVE
1  0.999    0.0015  0.0016  0.0016  0.0005  0.0011
2  0.995    0.0025  0.0027  0.0027  0.0012  0.0021
3  0.990    0.0032  0.0035  0.0035  0.0017  0.0029
4  0.950    0.0060  0.0065  0.0065  0.0044  0.0066
5  0.900    0.0083  0.0089  0.0089  0.0070  0.0099
6  0.850    0.0102  0.0110  0.0110  0.0095  0.0129
7  0.800    0.0120  0.0129  0.0130  0.0120  0.0158
8  0.750    0.0138  0.0148  0.0148  0.0146  0.0188
9  0.700    0.0155  0.0167  0.0167  0.0172  0.0218
10 0.650    0.0174  0.0186  0.0186  0.0201  0.0249
11 0.600    0.0192  0.0206  0.0206  0.0231  0.0282
12 0.550    0.0212  0.0227  0.0227  0.0265  0.0317
13 0.500    0.0233  0.0249  0.0250  0.0301  0.0356
14 0.450    0.0256  0.0273  0.0274  0.0341  0.0398
15 0.400    0.0281  0.0299  0.0300  0.0387  0.0445
16 0.350    0.0309  0.0329  0.0330  0.0439  0.0497
17 0.300    0.0341  0.0363  0.0363  0.0500  0.0559
18 0.250    0.0378  0.0402  0.0403  0.0573  0.0631
19 0.200    0.0424  0.0450  0.0451  0.0664  0.0720
20 0.150    0.0483  0.0512  0.0513  0.0784  0.0836
21 0.100    0.0566  0.0598  0.0600  0.0957  0.1000
22 0.050    0.0709  0.0747  0.0749  0.1263  0.1286
23 0.010    0.1049  0.1101  0.1103  0.2006  0.1963
24 0.005    0.1200  0.1257  0.1259  0.2334  0.2257
25 0.001    0.1556  0.1624  0.1627  0.3093  0.2935

```

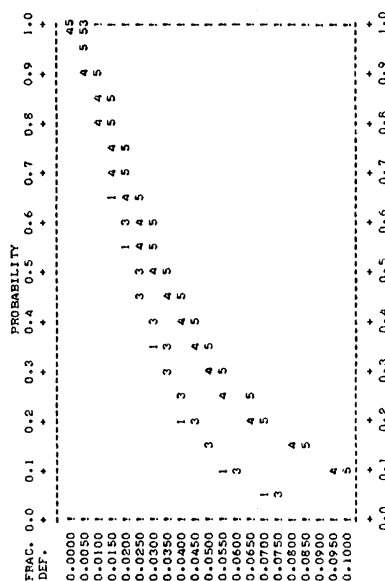


FIGURE 9--Input and output of program SL.OC.5 comparing the OC curves of five variable sampling plans.

in Figure 9 shows that by continuing to use $n = 10$ and by changing k from 1.9618 as given by program SL.2P.OC, to 1.9610, the output is: $p_1' = 0.0065$, $p_2' = 0.0600$, $\alpha = 0.05$, and $\beta = 0.10$, exactly as input significant to four decimal places.

Column 4 in Figure 9 is the OC curve for the MIL-STD-414 plan⁶ for size code G with an AQL of 0.65 percent. Column 5 is a similar plan developed by using program SL.2P.OC with input: $p_1' = 0.0065$, $p_2' = 0.1000$, $\alpha = 0.05$, and $\beta = 0.1000$.

DESIGN AND EVALUATION OF DOUBLE LIMIT VARIABLE SAMPLING PLANS

If it can be assumed that a process or lot is normally distributed, both lower and upper specification limits are required, and σ is known, three possible cases exist. In case one, with specification limits relatively close together and σ relatively large, it may be that the lot should be rejected without any sampling. This would be true if when the process average is centered between the upper and lower specification limits, the area under the two tails of a corresponding normal curve is still greater than the allowable fraction defective. Such a condition would exist given that Equation (2) were true:

$$\frac{U - L}{2\sigma} = z; \text{ and } (\Pr|z) \geq \frac{p'}{2} \quad (2)$$

where U = upper specification limit
 L = lower specification limit
 σ = known sigma
 z = standard deviation
 $(\Pr|z)$ = area under one tail of normal distribution at z sigmas
 p' = allowable fraction defective.

In case two with specification limits relatively far apart and σ relatively small, it should be possible to use two separate single limit variable sampling plans. These two plans could be designed easily by using program SL.2P.OC. This condition would be true if when the process average is centered between U and L there would be practically no defective material. A rule of thumb is to use two separate single limit variable sampling plans given that Equation (3) is true.

$$\frac{U - L}{\sigma} \geq 8. \quad (3)$$

Case three, where Equation (3) is not true, requires special treatment. Program DL.2P.FD was designed to cover this case where in a given lot there could be defectives both below the lower and above the upper specification limit.

PROGRAM "DOUBLE LIMIT, TWO POINT, FRACTION DEFECTIVE (DL.2P.FD)

To illustrate the use of program DL.2P.FD, let us consider a process manufacturing crystals for electronic equipment where the upper and lower specification limits and the known variation of the process are: $U = 27.107\text{MHz}$, $L = 27.104\text{MHz}$, and $\sigma = 0.0005\text{MHz}$. This process cannot be controlled by two single limit plans because Equation (3) is not true since:

$$\frac{U - L}{\sigma} = \frac{27.107 - 27.104}{0.0005} < 8.$$

Computer program DL.2P.FD is the proper tool to design a plan for this process. Let us assume that the producer is willing to take a 5 percent risk ($\alpha = 0.05$), that a lot with 1 percent ($p_1' = 0.01$) or less defectives (either above the upper or below the lower limit, or both) is rejected. Similarly the consumer is willing to take a 10 percent risk ($\beta = 0.10$) that a lot with 8 percent ($p_2' = 0.08$) or more defectives is accepted. Under these conditions we have established all conditions necessary to design and evaluate a plan for an acceptance sampling procedure for the crystals in our illustration.

```

/EXEC DL.2P.FD
% P500 000,DL2PFD,
***** IV PRIGRAN DL2PFD STARTED --- 12/21/77

PLEASE POST THE UPPER SPECIFICATION LIMIT (U)
*27.107
PLEASE POST THE LOWER SPECIFICATION LIMIT (L)
*27.104
PLEASE POST A VALUE FOR SIGMA
*0.0005
PLEASE POST THE VALUE OF P1
*0.01
PLEASE POST THE VALUE OF P2
*0.08
PLEASE POST THE VALUE OF ALPHA
*0.05
PLEASE POST THE VALUE OF BETA
*0.10
D YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER? (Y/N)
*Y

*****
* VARIABLE SAMPLING PLAN WITH DOUBLE SPECIFICATION LIMITS
* WITH KNOWN SIGMA AND LOWER OR UPPER TEST LIMITS
*****
* UPPER SPECIFICATION LIMIT = 27.1070
* LOWER SPECIFICATION LIMIT = 27.1040
* ESTIMATE OF SIGMA = 0.0005
* P1 = 0.0100 ALPHA = 0.0500
* P2 = 0.0800 BETA = 0.1000
* N = 10 K = 1.4117
*****
* PLAN:
* STEP 1: DRAW A RANDOM SAMPLE OF 10
* STEP 2: CALCULATE XBAR
* STEP 3: ACCEPT IF (XBAR - 27.1040)/0.0005 > 1.8107
* AND IF (27.1070 - XBAR)/0.0005 > 1.8107
* OTHERWISE REJECT
*****
* RELATIONS:
* XBAR = (U+L)/2
* L - XBAR = (U-L)/2
*****
* TABLE:
* SIGMA (S) SIGMA (S) SIGMA (S) P1 P2
* 1 27.1042 -0.3245 5.6756 0.3720 0.0000 0.3720
* 2 27.1043 -0.2476 5.4526 0.2920 0.0000 0.2920
* 3 27.1044 -0.1703 5.2297 0.2206 0.0000 0.2206
* 4 27.1045 -0.0936 5.0067 0.1403 0.0000 0.1603
* 5 27.1046 -0.2103 4.7838 0.1119 0.0000 0.1119
* 6 27.1047 -0.4392 4.5608 0.0750 0.0000 0.0750
* 7 27.1048 -1.6673 4.3378 0.0482 0.0000 0.0482
* 8 27.1049 -1.8852 4.1149 0.0397 0.0000 0.0297
* 9 27.1051 -2.1081 3.8917 0.0175 0.0000 0.0175
* 10 27.1052 -2.3311 3.6689 0.0099 0.0001 0.0100
* 11 27.1053 -2.5541 3.4460 0.0054 0.0003 0.0056
* 12 27.1054 -2.7770 3.2231 0.0027 0.0006 0.0036
* 13 27.1055 -3.0000 3.0000 0.0013 0.0013 0.0027
* 14 27.1056 -3.2229 2.7771 0.0006 0.0027 0.0034
* 15 27.1057 -3.4459 2.5542 0.0003 0.0053 0.0056
* 16 27.1058 -3.6688 2.3313 0.0001 0.0099 0.0100
* 17 27.1059 -3.8918 2.1082 0.0000 0.0175 0.0176
* 18 27.1061 -4.1147 1.8853 0.0000 0.0297 0.0297
* 19 27.1062 -4.3377 1.6624 0.0000 0.0482 0.0482
* 20 27.1063 -4.5607 1.4393 0.0000 0.0750 0.0750
* 21 27.1064 -4.7836 1.2164 0.0000 0.1119 0.1119
* 22 27.1065 -5.0066 0.9935 0.0000 0.1602 0.1602
* 23 27.1066 -5.2296 0.7704 0.0000 0.2205 0.2205
* 24 27.1067 -5.4525 0.5475 0.0000 0.2920 0.2920
* 25 27.1068 -5.6754 0.3246 0.0000 0.3727 0.3727
*****

```

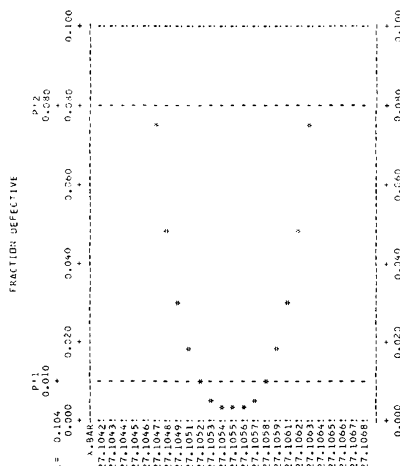


FIGURE 10-- Input and output of program DL.2P.FD for the design of a double limit variable sampling plan (σ known) with $U = 27.107$, $L = 27.104$, $\sigma = 0.0005$, $p_1' = 0.01$, $p_2' = 0.08$, $\alpha = 0.05$, and $\beta = 0.10$.

Figure 10 gives the plan in terms of the lower specification limit, the upper specification limit, the known σ , n , and k . These latter two values are calculated within the program by a well-documented procedure (see Duncan⁷). The tabulated part of Figure 10 shows: (1) \bar{X} values from samples of size 10 in column 1; (2) fraction defective because of product being below specifications in column 4; (3) fraction defective because of product being above specifications in column 5; and (4) the total of columns 4 and 5 in column 6. Values from column 6 are plotted against the \bar{X} values in the fraction defective plot.

Program "Double Limit, Unknown Sigma, Two Point, Fracture Defective" (DU.2P.FD)

When the variation of the process (σ) is not known, it is necessary to use a considerably larger sample (n) with a given acceptability constant (k) in order to obtain the same OC curve as for the case of a process with σ known. W. Allen Wallis⁸ offers special formulas for these cases. He indicates that for variable sampling plans where we do not know the lot or process standard deviation we must take a sample $(1+k^2/2)$ times as large as the sample size used in a plan with known σ . As discussed previously in connection with program DL.2P.FD, the situation of interest is "case 3" where Equation (3) is not true. This is required since with σ unknown we have no way of assuming a priori that case 1 or case 2 applies.

When there can be defective items both above the upper and below the lower specification limit simultaneously, any specific total fraction defective can be composed of an infinite number of combinations of upper and lower fraction defectives. Under this situation we cannot derive a single OC curve. However, a study by George L. Resnikoff⁹ shows that the OC curve derived for a single limit plan with specified p'_1 , p'_2 , α , and β is the lower limit of the band of OC curves for a two-sided specification plan with the same p'_1 , p'_2 , α , and β . For most practical cases, the OC curve for a single limit plan can be taken as the OC curve for the two-sided plan. In program DU.2P.FD we do not tabulate nor print out an OC curve but tabulate and plot the total fraction defective versus various \bar{X} values. This is similar to the output of program DL.2P.FD.

The actual calculation within program DU.2P.FD is quite complex and is based on work done by Resnikoff and Liebreman¹⁰ as described by Duncan.¹¹ In addition, the area under the tails of the distribution is calculated using the t distribution rather than the normal. A printout of program DU.2P.FD is shown in Figure 11. This figure does not include a plot of the OC curve since it is almost identical to the plot in Figure 10.

Comparison of Sample Size Between Attribute and Variable Sampling Plans

It is of considerable interest to compare the sample size from attribute sampling plans (program SS.2.POINT and SS.2P.HYPERG) discussed in an earlier paper by Schmid¹² to the sample size required by the two variable sampling plans discussed and illustrated in Figures 10 and 11. Attribute sampling using plans of the type given in MTL-STD-105D requires a sample size of 75 in this case. It is important to note that this type plan requires evidence that the process is stable. It was shown by Schmid¹³ that for the case of an isolated lot where no a priori knowledge about the process was available, the hypergeometric equation should be used and his program SS.2P.HYPERG gave a sample size of 124 for a lot of 600 (the lot size used in Figures 10 and 11).

Thus, an appropriate comparison between attribute and variable sampling plans for a lot of 600 with $p'_1 = 0.01$, $p'_2 = 0.08$, $\alpha = 0.05$, and $\beta = 0.10$ would be for a stable process: attribute (SS.2.POINT), $n = 75$ and variable (DL.2P.FD), $n=10$. Further for a process that is not known to be stable, i.e., σ is unknown: attribute (SS.P.HYPERG), $n = 124$ and variable (DU.2P.FD) $n = 27$. Thus, if variable sampling is possible and particularly if the process is stable and σ can be determined accurately, great savings may be made by using variable sampling plans tailored to the particular inspection problem.

DESIGN OF SINGLE LIMIT UNKNOWN SIGMA VARIABLE SAMPLING PLAN (SU.2P.OC)

As previously noted, Wallis⁸ has shown that unknown σ single limit variable sampling plans give substantially equivalent OC curves to known σ plans if n is multiplied by $(1 + k^2/2)$. Computer program SU.2P.OC uses this logic and tabulates and plots an OC curve almost identical to the known σ plans if n is multiplied by $(1 + k^2/2)$. Computer program SU.2P.OC uses this logic and tabulates and plots an OC curve almost identical to the known σ plan but calls for a much larger n . Figure 12 shows the input and output (without the OC curve) of program SU.2P.OC using the same input as was used with program SL.2P.OC (see Figure 8). As may be noted from these two figures, lack of a known value for σ requires an increase of sample size from 10 to 29 for this particular set of conditions.

```

/EXEC DU,2P,FD
% P500 000,DU2PFD.
FORTRAN IV PROGRAM DU2PFD STARTED --- 12/23/77

PLEASE POST THE UPPER SPECIFICATION LIMIT (U)
*27.107
PLEASE POST THE LOWER SPECIFICATION LIMIT (L)
*27.104
PLEASE POST THE VALUE OF P1
*0.01
PLEASE POST THE VALUE OF P2
*0.08
PLEASE POST THE VALUE OF ALPHA
*0.05
PLEASE POST THE VALUE OF BETA
*0.10
THIS PROGRAM REQUIRES A CALCULATED S IN THE SAMPLE SIZE N
FROM WHICH A NUMBER OF SAMPLE PLANS CAN BE CALCULATED. THIS
VALUE CAN BE INPUT OR IT CAN BE CALCULATED FROM SAMPLE DATA.

DO YOU HAVE A VALUE FOR S? (Y,N)
Y
PLEASE POST THE VALUE FOR S
*0.0005
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER? (Y,N)
N

```

```

*****
* VARIABLE SAMPLING PLAN WITH DOUBLE SPECIFICATION LIMITS *
* WITH UNKNOWN SIGMA AND BASED ON T DISTRIBUTION *
*****
* UPPER SPECIFICATION LIMIT = 27.1070 *
* LOWER SPECIFICATION LIMIT = 27.1040 *
* ORIGINAL ESTIMATE OF S = 0.0007 *
* P1 = 0.0100 ALPHA = 0.0500 *
* P2 = 0.0800 BETA = 0.1000 *
* N = 27 K = 1.6085 *
*****
* PLAN: *
* STEP 1: DRAW A RANDOM SAMPLE OF 27 *
* STEP 2: CALCULATE X.BAR *
* STEP 3: CALCULATE S *
* STEP 4: ACCEPT IF (X.BAR - 27.1040)/S >= 1.8085 *
* IF ( 27.1070 - X.BAR )/S >= 1.8085 *
* AND IF S <= 0.0007 *
* OTHERWISE REJECT. *
*****
* RELATIONSHIP BETWEEN X.BAR AND FRACTION DEFECTIVE *
* FOR A NORMALLY DISTRIBUTED PROCESS OR LOT *
*****
* (L - X.BAR) / (U - X.BAR) *
* P1 P2 *
* 1 27.1040 3.0000 6.0000 0.5000 0.0000 0.5000 *
* 2 27.1041 -0.2500 5.7501 0.4225 0.0000 0.4225 *
* 3 27.1042 -0.5000 5.5001 0.3510 0.0000 0.3510 *
* 4 27.1044 -0.7499 5.2501 0.2307 0.0000 0.2309 *
* 5 27.1045 -0.9999 5.0001 0.1633 0.0000 0.1633 *
* 6 27.1046 -1.2499 4.7501 0.1121 0.0000 0.1121 *
* 7 27.1047 -1.4999 4.5002 0.0738 0.0000 0.0738 *
* 8 27.1049 -1.7500 4.2501 0.0466 0.0000 0.0466 *
* 9 27.1050 -2.0000 4.0001 0.0281 0.0000 0.0281 *
* 10 27.1051 -2.2500 3.7501 0.0167 0.0005 0.0175 *
* 11 27.1052 -2.4999 3.5001 0.0098 0.0009 0.0107 *
* 12 27.1054 -2.7499 3.2501 0.0055 0.0016 0.0071 *
* 13 27.1055 -2.9999 3.0001 0.0031 0.0030 0.0039 *
* 14 27.1056 -3.2500 2.7500 0.0016 0.0055 0.0071 *
* 15 27.1057 -3.5000 2.5001 0.0009 0.0099 0.0107 *
* 16 27.1059 -3.7500 2.2501 0.0005 0.0169 0.0173 *
* 17 27.1060 -3.9999 2.0001 0.0002 0.0281 0.0283 *
* 18 27.1061 -4.2499 1.7501 0.0000 0.0466 0.0466 *
* 19 27.1062 -4.4999 1.5001 0.0000 0.0738 0.0738 *
* 20 27.1064 -4.7500 1.2500 0.0000 0.1121 0.1121 *
* 21 27.1065 -5.0000 1.0000 0.0000 0.1633 0.1633 *
* 22 27.1066 -5.2500 0.7501 0.0000 0.2308 0.2308 *
* 23 27.1067 -5.5000 0.5001 0.0000 0.3509 0.3509 *
* 24 27.1069 -5.7499 0.2501 0.0000 0.4224 0.4224 *
* 25 27.1070 -5.9999 0.0001 0.0000 0.5000 0.5000 *
*****

```

FIGURE 11-- Input and Output (without FD curve) of program DU.2P.FD for the design of a double limit variable sampling plan (σ unknown) with $U = 27.107$, $L = 27.104$, $p_1' = 0.01$, $p_2' = 0.08$, $\alpha = 0.05$, and $\beta = 0.10$.

DESIGN OF \bar{X} VARIABLE SAMPLING PLANS

Frequently manufacturers or users of bulk-type produce are interested in average quality rather than fraction defective, of the material being shipped or received. Two computerized variable sampling plans "Single Limit \bar{X} , OC" (SXB.OC) and "Double Limit \bar{X} , OC" (DXB.OC) will be discussed. Each gives assurance regarding the mean of the process or lot. The OC curve in both cases gives the probability of acceptance as a function of the process or lot mean.

Bulk-type materials for which \bar{X} sampling plans are useful is usually shipped in cans, barrels, tanks, bags, etc. It may be solid, liquid, or gas. In any event the samples taken from a lot of containers is considered mathematically as if they came directly from the process.

Program "Single Limit \bar{X} , OC" (SXB.OC)

Certain bulk products have a critical quality characteristic that can be evaluated or controlled relative to a single limit (either upper or lower). Program SXB.OC can be used to design a variable sampling plan for either an upper or lower limit; however, we will discuss only the lower limit case. Consider as an example a certain type light

```

DO YOU HAVE A VALUE FOR H AND K? (Y,N)
N
PLEASE POST P1 AS A FRACTION DEFECTIVE (AQL - "ACCEPTABLE
QUALITY LEVEL" AT THE PRODUCER'S RISK LEVEL OF PROBABILITY OF
REJECTION)
*0.0065
PLEASE POST P2 AS A FRACTION DEFECTIVE (LQ - "LIMITING
QUALITY" AT THE CONSUMER'S RISK LEVEL OF PROBABILITY OF
ACCEPTANCE)
*0.06
PLEASE POST A VALUE FOR ALPHA
*0.05
PLEASE POST A VALUE FOR BETA
*0.10
IS THIS A SINGLE UPPER LIMIT OR A SINGLE LOWER LIMIT PLAN (U,L)
L
WHAT IS THE LOWER LIMIT
*60.000
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER? (Y,N)
N
*****
* FRACTION DEFECTIVE VARIABLE *
* SAMPLING PLAN WITH SINGLE *
* SPECIFICATION LIMIT *
*****
* UNKNOWN SIGMA AND BASED ON *
* NORMAL DISTRIBUTION *
*****
* UPPER SPECIFICATION LIMIT = 68.0000 *
* P1 = 0.0065 ALPHA = 0.0500 *
* P2 = 0.0610 BETA = 0.1000 *
* N = 29 K = 1.9616 *
*****
* PLAN: *
* STEP 1: DRAW A RANDOM SAMPLE OF 29 *
* STEP 2: CALCULATE X.BAR *
* STEP 3: CALCULATE S *
* STEP 4: ACCEPT IF *
* (X.BAR - 60.0000)/S >= 1.9616 *
* OTHERWISE REJECT *
*****

```

FIGURE 12--Input and output (without OC curve) of program SU.2P.OC designing a single lower limit variable sampling plan with $p_1' = 0.0065$, $p_2' = 0.06$, $\alpha = 0.05$, and $\beta = 0.10$.

oil that is characteristically packaged in quart cans and distributed by the case of 24 cans. Let us say that specific gravity is the quality characteristic of interest and that the manufacturer feels any lot of this oil with a specific gravity of 0.795 or higher is "good" oil. He is willing to use a sampling plan that will reject no more than 5 percent of the lots with specific gravity of 0.795 or greater.

The customer agrees that oil with 0.795 specific gravity is "good" oil but he wants assurance that lighter oil is rejected. He states that he will agree to a sampling plan that will accept no more than 10 percent of the lots with a specific gravity of 0.790 or less. If from prior experience the standard deviation of the process is known to be 0.006, we have all of inputs required of program SXB.OC to design a variable sampling plan, i.e., $\bar{X}_1 = 0.795$, $\bar{X}_2 = 0.790$, $\alpha = 0.05$, $\beta = 0.10$, and $\sigma = 0.006$. Figure 13 shows both the input and output of program SXB.OC for the above example. The mathematics involved in program SXB.OC consider large lots as coming directly from the process, note that Figure 13 shows "infinite" as the lot size. Program SXB.OC also has a branch for small lots and for this condition uses $\sigma/\sqrt{(L-n)/n(L-1)}$ as the standard deviation of the sample instead of σ/\sqrt{n} . Newman¹⁴ shows that with a lot size of L

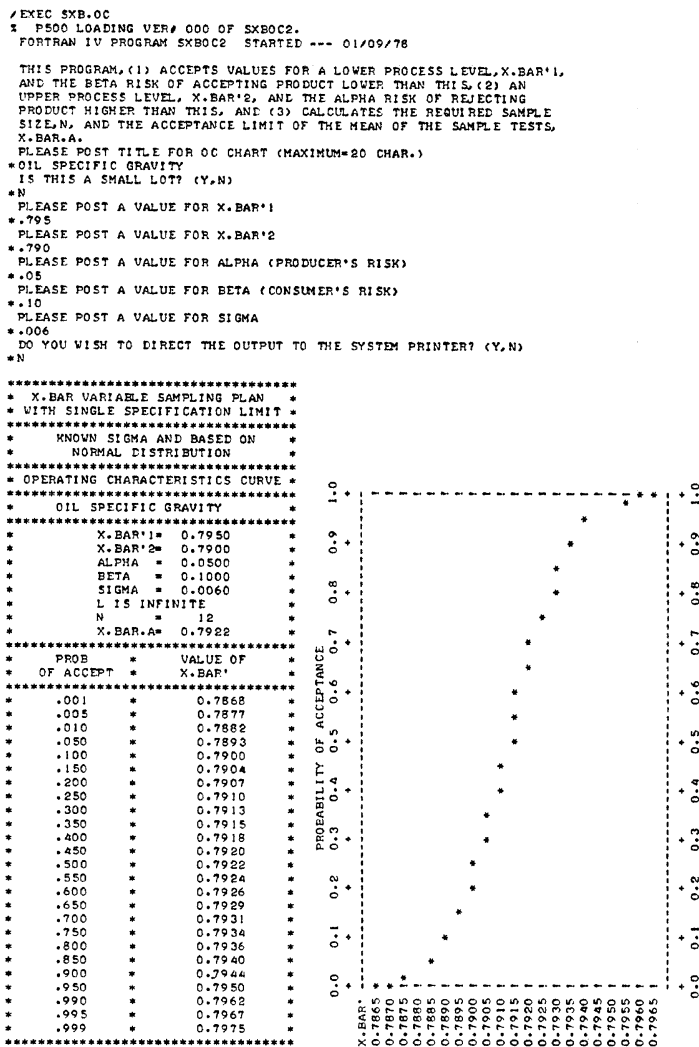


FIGURE 13--Input and output of program SXB.OC for the design of a single limit \bar{X} variable sampling plan with $\bar{X}_1 = 0.795$, $\bar{X}_2 = 0.790$, $\alpha = 0.05$, $\beta = 0.10$, and $\sigma = 0.006$.

and lot standard deviation of σ' , this adjustment is appropriate and results in a smaller sample size (n) for a given OC curve. Figure 13 was rerun using a lot size of 30. The printout (not shown) gives essentially the same OC curve but requires a sample size of only 9 as compared to 12 in Figure 13.

Program "Double Limit \bar{X} , OC" (DXB.OC)

Under certain conditions material from a bulk-type process is considered unsatisfactory if measurements of the quality characteristic of interest are either below or above a specified narrow band. If the process in question is known to be stable and if the standard deviation is known, it is possible to design a variable sampling plan with a very small sample size. However, this type plan puts severe constraints on the producer since he must keep the characteristic of interest exactly at the midpoint between the upper and lower specification limits to attain the specified producer's risk (α). Any deviation of the process average (either higher or lower) from the midpoint causes the producer's risk to increase. This is in contrast to single limit plans where the producer's risk continues to decrease when the process average becomes progressively higher than a lower specification limit (or progressively lower than a higher specification limit).

There are conditions, however, where a variable sampling plan with a very small sample size is attractive to both producer and consumer. This is particularly true if the producer has good control of the mean of the process and/or he can sell rejected product in a secondary market without excessive loss, i.e., good product that the sampling plan rejects can be sold elsewhere by discounting it only slightly.

Computer program DXB.OC designs such small sample plans. The operation of this program and the significance of the variable sampling plans designed can best be illustrated by example. Consider a certain alloy steel that must have both reasonably high tensile strength and high ductility. Let us say that it has been determined that if the tensile strength were 152,000 psi both requirements are satisfied well.

Let us assume that a producer has good control of his process, knows that the standard deviation of the process varies only slightly from its average value of 4,000 psi, and that he has a secondary market for all of this type alloy steel he can produce as long as it tests between 145,000 and 170,000 psi. Let us also assume that the primary user of this steel will agree to a sampling plan if he is required to assume no more than a 10 percent risk of accepting product less than 144,000 or greater than 160,000 psi. Under these conditions it is possible to design a variable sampling plan using program DXB.OC that requires a sample size of only 3 and still meet all constraints.

The inputs to program DXB.OC for this problem would be: upper specification limit ($U = 160,000$), lower specification limit ($L = 144,000$), variation ($\sigma = 4,000$), producer's risk ($\alpha = 0.05$), and consumer's risk ($\beta = 0.10$). There is one additional condition that should be tested before this program is used. This is that the upper and lower specification limits are reasonably far apart in relation to the σ of the process and the α and β values desired. Program DXB.OC may be used with confidence if Equation 4 is true:

$$U - L > 2(|z/\alpha| + |z/\beta|) (\sigma/\sqrt{n}). \quad (4)$$

For the example problem the absolute values of z/α and z/β are 1.96 and 1.28, therefore, Equation (4) is true for this case since:

$$160,000 - 144,000 > 2(1.96 + 1.28) (4000/\sqrt{3})$$

$$16,000 > 14965.$$

Computer program DXB.OC will be explained in reference to the problem just discussed. Figure 14 shows the process distribution [note items (1) and (2) in the

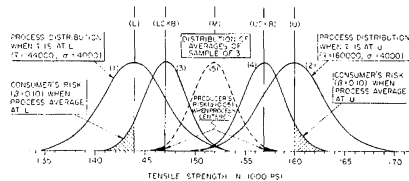


FIGURE 14-- Process distributions and distributions of samples of size 3 for the inputs to a typical design for program DXB.OC.

figure] when the process average is at the lower and upper specification limits respectively. Item (3) is the distribution of \bar{X} (LCXB) for sample size 3 centered at the lower control limit of \bar{X} ; item (4) is distribution of \bar{X} for sample size 3 centered at the upper control limit of \bar{X} (UCXB); and item (5), in a dashed line, is the distribution of \bar{X} for sample size 3 when the process is exactly centered between LCXB and UCXB.

When the process is exactly centered as may be seen in Figure 14 at the shaded areas under both tails of

distribution (5), there is a 5 percent chance of the lot being rejected ($\alpha = 0.05$), i.e., a 95 percent chance it will be accepted. This probability of acceptance decreases as the average of the process or lot either decreases or increases from the midpoint. When the \bar{X} of the sample is at LCXB, there is a 10 percent chance that the process or lot will be accepted when the actual process average is at or below the lower specification limit. Similarly, when the \bar{X} of the sample is at UCXB, there is a 10 percent chance that the process or lot will be accepted when the actual process average is at or above the upper specification limit.

```

/EXEC DXB.OC
* P500 LOADING VER# 000 OF DXB.OC.
FORTRAN IV PROGRAM DXB.OC   STARTED --- 01/09/78

PLEASE POST UPPER SPECIFICATION LIMIT (U)
* 160000
PLEASE POST THE LOWER SPECIFICATION LIMIT (L)
* 144000
PLEASE POST ALPHA (THE RISK OF REJECTING A LOT WHERE THE
TRUE MEAN IS WITHIN THE SPECIFICATION LIMIT)
* .05
PLEASE POST BETA (THE RISK OF ACCEPTING A LOT WHERE THE
TRUE MEAN IS OUTSIDE THE SPECIFICATION LIMIT)
* .10
THIS PROGRAM REQUIRES AN ESTIMATED VALUE OF SIGMA.
THIS VALUE CAN BE INPUT OR IT CAN BE CALCULATED
FROM SAMPLE DATA
DO YOU HAVE AN ESTIMATED VALUE FOR SIGMA? (Y,N)
* Y
PLEASE POST THE ESTIMATED VALUE OF SIGMA.
* 4000
DO YOU WISH TO DIRECT THE OUTPUT TO THE SYSTEM PRINTER?
* N

*****
* X-BAR SINGLE SAMPLING PLAN
* WITH DOUBLE SPECIFICATION LIMITS
* KNOWN SIGMA AND BASED ON NORMAL DISTRIBUTION
*****
* INPUTS: UPPER SPECIFICATION LIMIT (U) = 160000
* LOWER SPECIFICATION LIMIT (L) = 144000
* ESTIMATE OF SIGMA = 4000
* ALPHA = 0.05
* BETA = 0.10
*****
* PLAN 3: STEP 1: DRAW A RANDOM SAMPLE OF 3
* STEP 2: CALCULATE X-BAR
* STEP 3: ACCEPT IF X-BAR= 147217
* AND IF X-BAR=156783
* OTHERWISE REJECT
*****
* ALTERNATE PLANS
*
* PLAN 1    PLAN 2    PLAN 3
* UPPER CONTROL LIMIT 157040 156526 156783
* LOWER CONTROL LIMIT 146960 147474 147217
* SAMPLE SIZE      3      3      3
* ALPHA            0.0291 0.0500 0.0383
* BETA              0.1000 0.0663 0.0818
*****

```

FIGURE 15-- Input and output (without OC curve) of program DXB.OC for the design of a double limit \bar{X} variable sampling plan with $U = 160000$, $L = 144000$, $\sigma = 4000$, $\alpha = 0.05$, and $\beta = 0.10$.

output device, which will probably be a terminal. The third number specifies the high speed listing device used to produce massive output, most probably the system printer. With these three numbers changed to correspond to a given installation, the programs should compile and run on most systems.

Figure 15 is a printout (without the OC curve) of program DXB.OC for the problem just discussed. It will be noted that three different plans are posted. All three plans use a sample size of 3. The first plan establishes upper and lower control limits that exactly meet the consumer's risk (β), the second plan establishes control limits that exactly meet the producer's risk (α), and the third plan is a compromise between plans 1 and 2.

COMPUTER INDEPENDENT PROGRAMS

Each of the programs described in this paper (SL.F.DEF, SL.2P.OC, SL.OC.5, DL.2P.FD, SU.2P.OC, DU.2P.FD, SXB.OC, and DXB.OC) as well as other similar programs developed by the University of Dayton's School of Engineering are as computer-independent as possible. Each program is written in FORTRAN IV and is extensively commented. The programs are interactive and require a minimum hardware configuration of IBM 360/40, OS(64K). Because input and output facilities often differ between computers, it may be necessary to change one statement to make the programs work on a given installation. The program line (card) which needs to be changed is near the start of each program and is coded as follows:

DATA ITTYIN, ITTYOUT, ISYSPT /5,2,6/.

The purpose of this statement is to define the read and write logical unit numbers for the input and output devices of the computer on which the program is being compiled. The only numbers which need to be changed to fit any specific installation are the three numbers between the slashes. The first number specifies the unit number of the primary input device which will most probably be a terminal (time sharing). The second specifies the interactive

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2. Ibid, p 2
3. Ibid, pp 4, 91
4. Ibid, p 19
5. Duncan, Acheson J., Quality Control and Industrial Statistics, 4th Ed., Irwin, p 253-257.

6. MIL-STD-414, Op.Cit.,p 13
7. Duncan, Op. Cit.,pp 258-264
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9. Resnikoff, George L., A New Two Sided Acceptance Region for Sampling by Variables, Applied Mathematics and Statistics Laboratory, Stanford University, 1952.
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12. Schmid, Merle D., Design of Sampling Plans for Small Isolated Lots, Transactions of the 31st ASQC annual technical conference, Philadelphia, May 1977, p 579.
13. Ibid, p 582.
14. Newman, J. Contributions to the theory of small samples drawn from a finite population, Biometrika Vol XVII, pp 472-570.

223:70:00 0

PITFALLS IN QUALITY CONTROL MANAGEMENT

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INTRODUCTION

There are a number of colleges and universities in the country which offer excellent courses and curriculums in Quality Control Management. During their studies, students are exposed to those management practices which, historically, have proven to be effective. Indeed, the content of these courses represents the very best in "experience retrieval."

Most courses of study in Quality Control Management have a single, common shortcoming in that students are exposed to "the way to do things right" as opposed to "ways to avoid doing things wrong." An observation was once made that many successful people have succeeded not because they have achieved outstanding success, but because they have avoided outstanding failure.

The purpose of this paper is to present and discuss a number of things, or pitfalls, that a Quality Control Manager should avoid. Along with each pitfall described, a recommendation as to how to avoid the pitfall is presented. The subject matter has been drawn both from experience and observation. I trust that each reader will derive some measure of benefit from the pitfalls and recommendations presented herein.

PROGRAM ACTIVITY PITFALLS

Pitfalls of Disproportionate Action

1. The Pitfalls

- a. Over-Reaction: This pitfall, generally referred to as "overkill", is quite common, easy to get into, and difficult to refute at the time a course of action is proposed. Overkill can be disastrous to operating budgets and can destroy quality management credibility. Overkill must be minimized, but over-reaction to avoid this pitfall can be dangerous. It can lead to the next (and more serious) pitfall.
- b. Under-Reaction: This pitfall can seriously reduce product quality, multiply problem dimensions, and can destroy quality management credibility. Under-reaction frequently means "doing nothing", and initially, one may be applauded for doing nothing since it "doesn't rock the boat" and "doesn't produce political flak." But the problem, remaining unresolved, grows in significance until a catastrophic product failure or a quality reduction of some proportion appears. At this point, quality program credibility again comes under attack, massive corrective actions are begun, and the situation again becomes ripe for overkill or over-reaction.

Example: A company contracts with a supplier to manufacture a complex system. The supplier has trouble meeting his schedule. An under-reaction would be to take the position that it is the supplier's problem and do nothing. But this does nothing to help the overall problem. An over-reaction would be to send in a team of "Tigers" to expedite delivery of the systems. The systems are delivered but they will not meet quality requirements. The supplier is given little, if any, time to correct the hardware problems. The systems are installed in the end product, which cannot be delivered because the customer will not accept them. The company's cash register does not ring. The systems are returned to the supplier, and another tiger team goes to

expedite delivery again. This type of overkill is costly, delays schedule in the end, and delays revenue.

2. Avoiding the Pitfall

Avoiding this pitfall is difficult because human nature is involved. Further, middle and lower management tend to "overkill" a problem whenever top management appears to be concerned about a particular situation. To avoid this pitfall requires accurate assessment of "action and reaction" establish a "thought process." One first must ask himself the question: "What are the consequences of doing nothing?" Once that is assessed, the next question should be "In what way would I like for the situation to be changed?" Once that has been determined, one must ask this question: "What 'reasonable' courses of action are available which would tend to bring about the desired change?" Following this line of reasoning will not guarantee the identification of an optimum approach, but it has proven to surface the most appropriate course of action in many difficult and vexing instructions.

Pitfall of Limiting the Quality Audit Function to "Auditing" Rather Than "Auditing and Critiqueing"

1. The Pitfall

The basic responsibility of the quality audit function is to determine the degree of compliance to established quality procedures. Any deviation from or non compliance with the procedures is identified and corrective action initiated. Generally, personnel who have a good overall knowledge of the entire quality system are assigned to the quality audit function.

The pitfall in the above approach is that it does not provide a measure (1) of the adequacy of the procedures for all operations and activities, and (2) for evaluating the adequacy and compliance of the procedures with the contractual requirements. As a result, experienced auditors do not have an assigned responsibility to evaluate the very system being audited.

2. Avoiding the Pitfall

The auditor must be given free rein to evaluate the system being audited. This will result in recommendations that can minimize management surprises, and afford management a greater opportunity to utilize preventive actions rather than only corrective actions. Admittedly, it takes a special kind of person to effectively audit and evaluate at the same time. Further, there is the built-in potential for the auditor to inject "personality" comments into his critique of "what the quality system should be." However, properly approached, the vast experience of the auditor can be used to bring about desirable changes in the quality system.

Pitfall of not Changing Quality Systems and Techniques to Meet the Rapid Development of New Product Technology and Demands for Increased Product Performance

1. The Pitfall

Some quality systems or elements are not upgraded to meet the changes in product technology and increased customer performance requirements. Too often, we are prone to "make do" with what we have on hand. Knowing from experience the sometimes long, tedious and exhausting process of obtaining the necessary funding to procure new capital equipment only results in the request being rejected.

The need for mechanization of inspection and test equipment to maintain technical and cost effective quality control may not be properly planned. All these things will result in inadequate evaluations. Hand tools and gauges may not check all the parameters of a system, part or material. Materials that could once be visually inspected now may require analysis, both chemically and physically.

2. Avoiding the Pitfall

As a result of increased product technology and complexity, machine parts which were previously inspected by conventional layout inspection/hand measurement techniques, can now be inspected by computer control coordinate measuring systems. The computer is also an essential aid to our quality engineers, both in the initial generation of the part inspection program and the statistical analysis of the accumulated part inspection measurement data.

Another example of developing a new quality technique to meet new product technology involves the use of contact high resolution ultrasonics. This is a pulse echo technique with additional modifications/refinements utilized to evaluate questionable area(s) on graphite composite skins which have been located by another ultrasonic technique (immersion reflector plate). A "C" scan recording is produced by the immersion reflector plate technique revealing area(s) of question on those parts inspected. The questionable area(s) can be caused by several conditions, e.g., multi-level porosity, planer voids (voids on one plane), internal steps, external surface roughness and non parallelism to the reflector plate. By utilizing the contact high resolution technique, the inspector/operator can readily determine the source/cause of the questionable area(s) defined by the "C" scan recording. At the same time, the depth of the unacceptable condition can be determined.

Pitfall of Assuming That All the Design Engineering Experience Developed on Past Programs Will Be Carried Over to the Current Program

1. The Pitfall

There are a number of reasons that will reduce experience carryover from one program to the next: (1) retirements, (2) voluntary terminations, and (3) transfers. Further, new personnel will be added who do not have the experience to start with. But even the experienced personnel remaining can make the same mistakes again; such as these that have been found more than once: using tolerances that exceed the manufacturing capability or are not required to be as close as specified; failing to specify torque values; deviating from specifications (machine finish, hole sizes, bend radii, etc.); using improper processes (heat treat, chemical treatment, finish, etc.); use of improper process/NDT; using new materials without sufficient data to support the applications; failing to specify controls or specifying inadequate controls/documents; and, failing to impose contractual requirements.

2. Avoiding the Pitfall

This pitfall can be avoided almost entirely through the implementation of a quality control review of engineering drawings and specifications prior to their release. On one program, prior to actually initiating such a review, an extensive and intensive study was made of past program problems which developed as a result of poor quality callouts (or lack thereof) on engineering drawings and specifications. An output of this study was a set of checklists of the kinds of callouts that drawings and specifications should contain -- for each type of product produced by the company, i.e., electrical, electronic, mechanical, electromechanical, forgings, castings, machined parts, etc. These checklists were coordinated with most experienced people in the company in functions such as Quality Control, Manufacturing, Engineering, Material, Tooling and Test Laboratories. As a result of this coordination, the checklists were further improved re proper quality control callouts on engineering drawings and specifications. Armed with this kind of "experience retrieval", the people in the Quality Control Drawing and Specification Review Group brought about changes in the drawings and specifications prior to their initial release -- changes which represented approximately four million dollars in cost avoidance! From this example, it can be seen that avoiding this pitfall can be self serving.

Pitfall of not Insisting on Real Corrective Action for Discrepancies/Problems

1. The Pitfall

People are inclined to avoid taking the responsibility for causing a discrepancy or a problem. First of all, it is human nature to do so. No one wants a reputation for making mistakes or errors. One's personal sense of self-esteem is brought into view when responsibility and "blame" are being assigned. Second, in a "cost accountability" oriented organization, the cost of rework and scrap is charged to the responsible department. These costs are often an influence on performance evaluations and salary reviews. Further, when people cannot completely elude personal responsibility, they tend to be non committal and give vague, superficial statements of corrective action to be taken. This tendency is to be expected since a firm commitment of corrective action is an admission of sorts that one is responsible for the problem. As a consequence, since the promised corrective action is vague and superficial, often these actions are never carried out or are deferred indefinitely.

There is a multitude of other reasons why real corrective action is frequently never identified and implemented. Even the people who are responsible for ferreting out corrective action have "schedule" problems. It seems that there is never time to get to the root of a problem and solve it. It seems that there is no time to make the part right the first time, but there is always time to fix it. Vendors are reluctant to take corrective action that will invoke cost. Employees sometimes fix discrepancies without reporting them. When corrective action is implemented, too often we fail to verify the implemented corrective action is actually effective.

2. Avoiding the Pitfall

What is about to be said here may sound familiar, but it is fact and should be heeded every day! Trying to avoid the problem is costly. Often, more time and money is wasted in eluding and evading a problem than it would cost to solve the problem in the first place.

The only method that has proved effective in avoiding this pitfall (and it has proven so time and time again) is the implementation of a closed-loop corrective action system.

The basic and necessary elements of such a system are described below:

- a. Identification Responsibility: A matter of specific assignment has to be made to review discrepancy/problem data to identify those trends and/or significant single events that should be investigated for corrective action identification purposes. An alternative would be to investigate all discrepancies/problems without exception; however, few of us are blessed with the unlimited resources that would be required to implement this alternative.
- b. Investigation Responsibility: A matter of specific assignment has to be made to investigate selected trends and significant single events to identify specific corrective action that will eliminate the problem or reduce the likelihood of its recurrence. Corrective action of this nature is frequently referred to as "positive" and is based on identification of the specific root cause or failure mechanism of the discrepancy or problem.
- c. Implementation Responsibility: Once the necessary corrective action has been identified, it must be implemented to be effective - a truism. On the assumption that "the fix" is less costly than "living with the problem" there has to be a commitment of the resources necessary to implement the identified corrective action. This tradeoff may involve top management. However, even if corrective action is implemented, a closed-loop system is not necessarily attained.
- d. Evaluation Responsibility: At some point in time after the corrective action has been implemented, someone must evaluate the efficaciousness

of the action. At this point one of two possible decisions must be made. First, if it is decided that the implemented corrective action produced the desired result, no further action is necessary. Second, if it is decided that the desired result was not produced, a decision must be made. A matter of specific assignment has to be made to investigate selected trends and significant single events to identify specific corrective action that will eliminate the problem or reduce the likelihood of its recurrence. Corrective action of this nature is frequently referred to as "positive" and is based on identification of the specific root cause or failure mechanism of the discrepancy or problem. Anything short of this cycle does not constitute a closed-loop system.

PITFALLS IN WORK INSTRUCTIONS

Pitfall of Believing Written Material Will Always Be Understood

1. The Pitfall

A good technical writer is rare indeed. If you have one in your organization, treat him well, because your technical instructions and literature, if not well written, can result in the unnecessary expenditure of many dollars.

The most common cause of issuing work instructions that are not understood is attributed to the difference in the average education of the worker and the equivalent average education of the work instructions. On one program considerable difficulty with work instructions was experienced, i.e., it seemed the workers were not reading the instructions. A comparison of the worker and the work instructions was finally made (it requires a specially trained person to do this). It was determined that the average education level of the worker was equivalent to eleven and one-half years of high school and that the average education level of the work instructions was one and one-half years of college. Once the instructions were rewritten to the level of the worker, the "work instruction" problem disappeared.

2. Avoiding the Pitfall

If you do not have a good technical writer in your organization, get one, for no matter how understandable a written document appears, there is a better-than-even chance that someone will misinterpret that document. Murphy's Law will always apply to written instructions.

If you are ever in a situation and begin to think that "everything would be alright if the workers would follow the procedure", you are likely to be in a situation where the work instructions need attention. In most cases, the worker will not be at fault.

Pitfall of not Maintaining and Upgrading Work Instructions

1. The Pitfall

Maintenance of documents may be relegated to a routine category with insufficient technical and management support. More emphasis may be placed on the auditing of work instructions rather than the development and refinement of those work instructions. Serious quality problems are sometimes traced to conflicting or otherwise inadequate work instructions. When this situation occurs renewed effort is expended to upgrade and update the affected work instructions.

Another aspect of this pitfall is that almost all work instructions refer to one or more other work instructions for additional guidance. The referenced document in turn refers to others. Recently, a case was reported where a worker was referred to fifty separate work instructions in performance of a relatively simple assembly task.

2. Avoiding the Pitfall

People fall into this pitfall because there is seldom a planned review and

revision of an entire body of work instructions at the outset of a program. At the outset of each new program, all existing work instructions must be reviewed to determine the current degree of applicability. There is nothing worse than trying to do a job with an out-of-date procedure. The out-of-date portions of work instructions should be cancelled immediately. The "not perfectly clear" portions should be upgraded; and, certainly, new instructions should be prepared, proofed and released where needed.

The latter aspect of the pitfall indicated above, where a document referenced fifty other documents, can be avoided. "Built-in" problems of this type can usually be identified if a requirement exists to demonstrate in an actual working environment the adequacy of each work instruction prior to its release. The time wasted in looking up endless references to other documents will surely be highlighted. By this means, the need to issue self-contained work instructions will be highlighted to management's attention.

Pitfall of not Enforcing Work Instructions

1. The Pitfall

Management may approve or direct the issuance of written directives, policies and procedures, and then fail to provide the impetus for enforcement. Such action, or inaction, seriously degrades the effectiveness of the entire written communication system.

2. Avoiding the Pitfall

A cardinal rule should be to issue only those written communications essential to efficient operation and then to insist upon absolute adherence. To do otherwise would be to issue an instruction that should be followed "some of the time." This would lead to individual and mass confusion and invariably will lead to higher quality costs through increased reject and scrap rates. If a worker, for any reason, cannot follow an instruction, the situation must be surfaced so that a determination can be made as to whether corrective action is needed in the instruction, tooling, engineering, planning, etc.

Pitfall in not Having a Planned Time-Phased Schedule for Auditing Compliance to Written Instructions

1. The Pitfall

Based on experience, I would be willing to wager that if I sent an audit team into the facilities represented here, the largest category of identified discrepancies would be "failure to follow established procedures." The thought boggles the mind -- after all the time and money we spend on written work instructions, on training people to understand their assigned tasks, the most common audit finding is "failure to follow established procedures."

2. Avoiding the Pitfall

A good, thorough quality system audit function is the only continuously effective mechanism to constantly reinforce the practice to "follow the instructions or request a revision to them." This reinforcement must be coupled with frequent attention by the first line supervisor.

ADMINISTRATION PITFALLS

Pitfall of Trying To Do Everything Yourself

1. The Pitfall

Good managers will attempt to staff their departments with top-notch personnel at every level. Why? Because top-notch personnel can be trusted to "get the job done." Please note that trusting your personnel to "get the job done" implies a high degree of delegation. Webster defines the word "delegate" as "one sent and empowered to act for another." Yet,

how many times do we boast about the high caliber of our people and then elect not to delegate them authority commensurate with their assessed capability!

For those of us who practice the art of delegation, I am sure that we can remember telling someone that they "have the ball" to get something done, and then call frequently to ask, "How is it going?" or "Are you on schedule?" or "Have you run into any problems yet?" That is not delegation.

The eighteenth chapter of Exodus in the Bible describes a problem of a manager trying to do everything himself. In this story, Moses spent vast amounts of time judging the cases brought to him. Jethro, Moses' father-in-law, was there and observed all this. He advised Moses to delegate authority to judge to the captains-of-ten, captains-of-hundreds, captains-of-thousands, etc. Jethro explained, "Every small matter they shall judge, but every great matter they shall bring to thee." Not only was this good delegation, but it is also a good example of the principle of management by exception.

2. Avoiding the Pitfall

There are two basic points to remember in delegating authority. First, solicit your people's assistance in defining the task. In doing this, detail the task only to the degree necessary; leave them room to exercise their own experience and know-how. Second, require meaningful feedbacks only to the degree necessary for control. In short, allow your subordinates to do their job and focus your attention on managing.

Pitfall of Reluctant Decisions Regarding Personnel

1. The Pitfall

One of the major pitfalls of management, even Quality Assurance management, is the hesitation or reluctance to reassign or terminate an employee who is judged to have marginally satisfactory performance. Such hesitation is not fair to the company or to yourself, but most of all, it is not fair to the employee since it tends to leave the employee in a job in which the employee has little opportunity, if any, to advance.

2. Avoiding the Pitfall

A manager has a responsibility to find the "right" job for everyone in his department. Further, the manager has the responsibility to provide each employee such training and orientation as may be necessary for the employee to perform at a fully satisfactory level. After all this is accomplished and the employee is still a marginal performer, then further action must be taken.

Sure, there is the personal trauma on both sides when the manager has to tell an employee, face-to-face, that the employee's performance is only marginally satisfactory and that termination of employment with the company is imminent. But this is really a merciful act. Think of the heartbreak and frustration on the part of an employee when left indefinitely in a job where probably the employee will never be a top performer, and when the employee will have little if any consideration for promotion or increases in salary.

PERSONNEL QUALITY DEVELOPMENT PITFALLS

Pitfall of not Encouraging Personnel to Join ASQC

The American Society for Quality Control is an organization dedicated to the advancement of the theory and practice of quality control and of the allied arts and sciences, and for the promotion of high professional standing among its members. Not being a member is equivalent to being deprived of the most valuable source of information about quality control in the world.

Publications Available to ASQC Members

1. Quality Progress: Published monthly and contains articles of general interest plus news of the profession, the Society and its units.
2. Journal of Quality Technology: Published quarterly and contains papers which emphasize the practical applicability of new techniques, instructive examples of the operation of existing techniques, and results of historical research.
3. Technometrics: Published quarterly, jointly by ASQC and the American Statistical Association and contains articles of the development and use of statistical methods.

Education and Training

ASQC has developed a program of professional short courses, such as Managing for Quality, Quality Engineering, Management of Quality Costs, Advanced Statistics for the Quality Practitioner, and Management of the Inspection Function.

Certification

Certification examinations are offered for Certified Quality Engineer (or Technician) and Certified Reliability Engineer (or Technician).

Annual Technical Conference

Those who can attend greatly profit by doing so. This is an annual opportunity to personally meet leading quality practitioners from all over the world -- to talk with them, to exchange ideas and questions. Those who cannot attend can obtain a copy of the Transactions which contains much valuable information on every aspect of quality.

Participation

For those who wish to actively participate, good people who wish to work are always welcomed on one or more of the many Society Sections, Divisions and Committees. For information on any aspect of the Society, people should feel free to contact the Society Headquarters in Milwaukee.

LCS 330:10:000

METHODOLOGY CLASSIFICATION000: GENERAL

010: Quality Definitions/Symbols
2.2.7B

020: Quality Systems
1.3.2A, 2.1.3A, 2.2.3C, 2.3.3C,
1.1.5C, 1.3.5C, 1.2.6B, 3.3.6B,
2.2.7C

030: Product Performance
2.2.3B, 3.1.5B

100: STATISTICAL PROCESS CONTROL

112: Control Charts for Attributes
1.1.6A

114: Cumulative Sum Charts
S6

123: Process Capability
3.1.3A

200: SAMPLING

220: Sampling Plans
2.3.5B

221: Selection/Comparison of
Sampling Plans
2.3.1C

222: Attributes Plans
2.2.4C, 3.3.4B, S9

223: Variables Plans
1.2.6A, S11

300: MANAGEMENT OF QUALITY ASSURANCE

2.1.2A, 1.1.3C, 1.2.3B, 3.3.3C,
3.3.5C, 2.1.6A, 2.2.6A, S10

310: Implementing Quality Programs
1.2.1B, 3.1.2A, 3.2.2A, 1.3.3A,
1.2.4B, 1.3.4A, 2.3.4B, 2.3.4C,
3.2.5C, 2.2.6C, 1.2.7, S1

320: Training and Education
1.1.3B, 1.1.4A, 3.3.5B

330: Organization for Quality
1.3.2C, S12

331: Quality Personnel
2.1.6B

340: Administrative Techniques
in Quality
2.1.4B, 1.1.5A, 1.3.6A

341: Records and Reports
2.2.4A, 3.2.4B, 3.2.4C

342: Standards and Procedures
1.2.2B, 1.2.2C, 3.2.2C, 2.2.4D,
1.1.5B, 2.2.7A

345: Quality Audits/Surveys
2.1.2B, 1.1.3A, 2.3.3B, 3.2.4A, S8

346: Document Control
3.3.5C

350: Economics of Quality
1.2.3C, 3.2.7B, 3.2.7C

351: Customer-Vendor Relations
1.1.1B, 2.3.1A, 3.1.1, 3.2.1,
3.2.3B

352: Quality Standards
2.3.1B

353: Quality Cost Measurement
1.2.4C, 1.1.7A, 3.1.7A, 3.2.7A

354: Product Safety and Liability
2.1.5C, 2.2.5C, 2.3.5A

400: MATHEMATICAL STATISTICS AND
PROBABILITY

2.3.6B

420: Distribution Functions
2.2.6B

430: Probability Theory
2.2.4B

500: EXPERIMENTATION STATISTICS

510: Tests of Significance and
Confidence Intervals
1.1.6C

530: Correlation
3.2.3A

540: Curve Fitting (Regression)
2.3.6A

545: Time Series
1.1.6B

600: MANAGERIAL APPLICATIONS

620: Industrial Engineering
1.1.4C

630: Business Economics
3.3.5A

640: Data Processing and Data
Processing Applications
2.1.4A, 2.1.4C, 2.3.4A, 1.2.5C, S3

FUNCTIONAL CLASSIFICATION

670: Industrial Psychology and Quality Motivation
1.1.2A, 1.3.3B, 2.1.3B, 2.1.3C, 1.2.4A,

680: Human Factors/Engineering
3.3.2A

700: MEASUREMENT AND CONTROL
2.2.2B, 2.2.3A

710: Measurement of Quality Characteristics
1.3.1, 2.3.2A, 1.2.5B, 3.2.5B

720: Process Control
3.2.2B, 3.1.3B

730: Data Handling
1.1.1C

750: Destructive/Nondestructive Examination
3.3.2C

760: Inspection
3.1.2B

770: Testing/Operating
2.2.2A

790: Corrective Action
3.1.4B

800: RELIABILITY
1.1.1A, 2.1.1B

811: Organization
3.1.4C

824: Estimating and Assessment
2.3.7A

840: Methods of Reliability Analysis
2.2.1B

850: Reliability Demonstration/Measurement/Testing
1.2.1A, 2.1.1A, 2.2.1C

870: Maintainability
3.1.4A

:00: General
2.1.5C, 3.3.5B, 1.1.6B, 1.2.6C, 2.2.7A, 2.2.7B, 2.3.7A

:10: Management
1.1.2A, 1.2.2B, 1.3.2C, 2.1.2A, 3.1.2A, 3.3.2A, 1.1.3A, 1.1.3C, 1.2.3B, 1.3.3A, 2.1.3A, 2.3.3B, 3.3.3C, 1.2.4B, 2.1.4B, 2.2.4D, 2.3.4B, 1.1.5C, 2.2.5C, 3.3.5A, 1.2.6B, 1.3.6A, 2.1.6A, 3.2.6B, 1.1.7A, 1.2.7, 3.1.7A, 3.1.7B, S8, S12, 2.2.6A

:20: Production
3.2.2B, 3.1.3B, 1.3.4A, S3, S6

:30: Financial
3.1.7A

:40: Procurement
2.3.1A, 3.1.1A, 3.2.1, 2.2.2A, 3.2.3B, S10

:60: Engineering
1.3.1, 2.1.1A, 2.2.1C, 2.3.1B, 2.2.3B, 3.1.3A, 3.2.3A, 3.1.4A, 3.1.5B, 3.2.5C, 2.3.5A, 2.2.6B

:70: Quality
1.1.1A, 1.1.1B, 1.1.1C, 1.2.1A, 1.2.1B, 2.1.1B, 2.2.1B, 2.3.1C, 1.2.2C, 1.3.2A, 2.1.2B, 2.2.2B, *3.1.2B, 3.2.2A, 3.2.2C, 3.3.2C, 1.3.3B, 2.1.3B, 2.1.3C, 2.2.3A, 2.2.3C, 2.3.3C, 1.1.4A, 2.1.4A, 2.1.4C, 2.2.4A, 2.2.4B, 2.2.4C, 2.3.4C, 3.1.4B, 3.1.4C, 3.3.4B, 1.1.5A, 1.1.5B, 1.1.5C, 1.2.5A, 1.2.5B, 1.2.5C, 1.3.5C, 2.3.5B, 3.2.5B, 3.3.5C, 1.1.6A, 1.2.6A, 1.3.6B, 2.1.6B, 2.3.6A, 2.3.6B, 2.2.7C, 3.2.7C, S1, S9, S11, *2.3.2A

:80: Industrial Relations
1.2.4

:90: Management Services
1.1.3B, 1.1.4C, 1.2.4C, 2.3.4A, 3.2.4A, 3.2.4B, 3.2.4C, 2.2.6C

INDUSTRY AND BUSINESS CLASSIFICATION

:000 GENERAL OR NON-CLASSIFIABLE

ESTABLISHMENTS

2.3.1C, 3.1.1, 3.2.1, 1.1.2A,
1.2.2B, 2.1.2A, 3.1.2A, 1.1.3A,
1.1.3C, 1.2.3B, 1.2.3C, 2.3.2A,
1.3.3A, 1.3.3B, 2.1.3A, 1.2.4A,
2.1.4A, 2.1.4C, 3.2.4A, 3.3.5A,
3.3.5B, 1.1.6A, 1.1.6B, 1.2.6A,
1.2.6B, 1.2.6C, 1.3.6A, 1.3.6B,
2.1.6A, 2.3.6B, 3.3.6B, 1.1.7A,
2.2.7A, 2.2.7B, 2.2.7C, 2.3.7A,
3.1.7A, 3.2.7A, 3.2. B, S8, S9,
S11, S12 2.1.6B
2.1.3A, 2.1.3B, 3.2.3A, 1.1.4A,

:400 MANUFACTURING

2.1.1B, 2.2.1C, 3.3.2A, 2.1.3C,
2.3.3C, 3.1.3A, 1.3.5C, 2.2.5C,
2.3.5B, 3.2.7C, S3, S6

:420 Food and Kindred Products
2.2.6B

:425 Furniture and Fixtures
3.2.5C

:428 Chemicals and Allied Products
3.3.5C, 2.3.6A

:433 Primary Metal Industries
3.3.3C

:434 Fabricated Metal Products,
Except Ordnance, Machinery
and Transportation Equipment
2.2.3B, 2.2.3C, 3.3.4B

:435 Machinery, Except Electrical
2.2.4A, 3.2.4B

:436 Electrical Machinery, Equip-
ment and Supplies
1.1.1C, 2.2.2A, 3.1.3B, S10

:437 Transportation Equipment
2.1.1A, 2.2.1B

:438 Professional, Scientific, and
Controlling Instruments;
Photographic and Optical
Goods; Watches and Clocks
3.3.2C, 3.2.4C, 1.1.5C

:439 Miscellaneous Manufacturing
Industries
1.1.1A, 1.1.1B, 1.2.1B, 1.3.1,
2.3.1A, 2.3.1B, 1.3.2C, 3.1.2B,
3.2.2A, 3.2.2B, 2.2.3A, 3.2.3B,
1.2.4B, 2.2.6C, 1.2.7

:500 TRANSPORTATION, COMMUNICATIONS, ELECTRIC, GAS, AND SANITARY SERVICES

:545 Transportation by Air
2.2.4D

:549 Electric, Gas and Sanitary
Services
2.1.2B, 2.2.2B, 1.1.3B, 2.3.3B,
3.1.4A, 3.1.4B, 3.1.4C

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3.2.5B

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1.3.4A

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1.2.5A, 1.1.5B

:870 Hotels, Room Houses, Camps,
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2.2.6A

:873 Miscellaneous Business Services
1.1.4C

:880 Medical and Other Health
Services
1.1.5A, 1.1.5B, 1.2.5A, 1.2.5B,
1.2.5C

:882 Education as Services
2.3.5A

:886 Nonprofit Membership
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3.1.5B

:889 Miscellaneous Services
1.2.4C

:900 GOVERNMENT

:991 Federal Government
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1.2.2C, 2.1.5C

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